P990027

Summary of Safety and Effectiveness Data

I. GENERAL INFORMATION

Device Generic Name:	Ophthalmic Excimer Laser System
Device Trade Name:	TECHNOLAS®217A Excimer Laser System
Applicant's Name and Address:	Bausch & Lomb Surgical, Inc. 9342 Jeronimo Road Irvine, California 92618
Date of Panel Recommendation:	None
Premarket Approval Application (PMA) Number:	P990027
Date of Good Manufacturing Practice (GMP) Inspection:	May 5-8, 1998
Date of Notice of Approval to Applicant:	February 23, 2000

II. INDICATIONS FOR USE

The Bausch & Lomb Surgical TECHNOLAS® 217A Excimer Laser System is intended for use:

- In laser in situ keratomileusis (LASIK) treatments for the reduction or elimination of myopia between -1.00 and -7.00 diopters (D) of sphere and less than -3.00 D of astigmatism at the spectacle plane.
- In patients with documented evidence of a change in manifest refraction of less than or equal to 0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination.
- In patients who are 21 years of age or older.

III. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

A. Contraindications:

LASIK surgery is contraindicated in:

- Patients with collagen vascular, autoimmune, or immunodeficiency diseases;
- Pregnant or nursing women;
- Patients with signs of keratoconus;
- Patients who are taking one or both of the following medications: isotretinoin (Accutane), or amiodarone hydrochloride (Cordarone).

B. Warnings and precautions

Please refer to the professional Use Information and the patient Information Booklet for a complete list of Warnings and Precautions.

IV. DEVICE DESCRIPTION

The TECHNOLAS®217A Excimer Laser System is designed for the correction of refractive error by reshaping the surface of the cornea. Corneal reshaping is accomplished by ablating precise amounts of corneal tissue with high-energy ultraviolet light from a pulsed argon-fluoride excimer laser system. The desired ablation profile is based upon the thin lens equations. The TECHNOLAS®217A uses a small diameter spot in a scanning mode to create the type of correction desired – myopia or astigmatism.

The TECHNOLAS®217A Excimer Laser System consists of the following components:

Laser Unit	The laser unit consists of the laser head (discharge system), which contains the optical resonator and a discharge chamber, which is filled with a premix of argon, fluorine, and a buffer of other noble gases.
Control Unit	The control unit contains the personal computer that uses a software algorithm to calculate the number and location of laser pulses required to achieve the desired correction.
Tower Unit	The tower unit provides the stable holding construction for the optical system of the TECHNOLAS®217A Excimer Laser. The tower unit contains the optical elements that condition the laser beam to the appropriate characteristics. The tower also contains the visualization optics (the operating microscope) and the positioning and fixation optics for properly locating and monitoring the progress of the ablation. There is a distance of 21 cm ("working distance") between the focusing point on the cornea and the laser arm.
Operating Elements	The operating elements of the TECHNOLAS®217A Excimer Laser System consist of two joysticks for movement of the patient bed in all axes and other operating elements and external connectors.
Bed Unit and Chair	The bed unit allows for accurate positioning of the patient during the surgical procedure while the operating chair allows the surgeon to adjust his/her position at the operating microscope.

TECHNOLAS®217A Excimer Laser Specifications

Laser Type:	Argon Fluoride
Laser Wavelength:	193 nm
Laser Pulse Duration:	18 nanoseconds
Laser Head Repetition Rate:	50 Hz
Effective Corneal Repetition Rate:	12.5 Hz
Fluence (at the eye):	120 mJ/cm^2
Range of Ablation Diameter:	2.0 to 2.05 mm

The LASIK procedure requires the use of a commercially available microkeratome that has been cleared for marketing via premarket notification. An automated microkeratome was used in the clinical studies to make a very precise thin flap of tissue of pre-selected thickness and diameter on the cornea. This flap is then folded out of the way, and the excimer laser is used to flatten the front surface of the cornea below the flap. The cornea is held in position by a suction ring, with a geared drive mechanism on the suction ring used as a track for the motorized microkeratome.

V. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative methods of correcting nearsightedness (myopia) include: eyeglasses, contact lenses, photorefractive keratectomy (PRK), incisional refractive keratotomy (RK), and lamellar refractive keratotomy.

VI. MARKETING HISTORY

Over 160 TECHNOLAS®217 Excimer Laser Systems have been installed in the following countries:

Argentina, Australia, Austria,
Belgium, Brazil,
Canada, Chile, China, Colombia, Czech Republic,
Finland, France,
Germany, Greece,
Hong Kong,
India, Indonesia, Israel, Italy,
Japan, Jordan,
Korea,
Malaysia, Mexico,
New Zealand,
Portugal,
Qatar,
Russia,
Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland,
Thailand, Turkey,
United Kingdom, and
Venezuela

The TECHNOLAS®217A Excimer Laser System has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential adverse events of this device include: loss of best spectacle corrected visual acuity, worsening of patient complaints such as double vision, sensitivity to bright lights, increased difficulty with night vision, fluctuations in vision, increase in intraocular pressure, corneal haze, secondary surgical intervention, corneal

infiltrate or ulcer, corneal epithelial defect, corneal edema, problems associated with the flap including a lost, misplaced or misaligned flap, retinal detachment, and retinal vascular accidents.

Please refer to the complete listing of adverse events and complications observed during the clinical study which are presented in Table 10.

VIII. SUMMARY OF PRECLINICAL STUDIES

A. Objectives

The following preclinical tests were conducted to establish the safety and performance of the TECHNOLAS® 217A Excimer Laser System:

- Functionality Testing
  Fluence Test was performed prior to each treatment using 50 pulses at 2 alternating spot positions.

- Reliability Testing
  Laserhead Lifetime, Gas Lifetime and Shutter Life-cycle Testing demonstrated that the laserhead has a linear drop-off over 10 days for passive lifetime and linear drop-off over 500,000 shots. The laserhead is stable and provides sufficient energy per treatment. The passive gas lifetime is 10 days and dynamic lifetime is 500,000 shots at 5,000 shots per cycle. The shutter was tested for 200,000 with no failures.

- Albation Studies – similar to Spherical Munnerlyn with the addition of a small zone at the edges.

- Electrical Safety and Electromagnetic Compatibility Testing
  The device conforms to IEC 601-1 General Electrical Safety; EN 60601 Requirements for Safety; EN 60601-1-2 EMC; and IEC 601-2-22 Safety of Diagnostic and Laser Equipment.

- Software Verification Testing provided acceptable documentation demonstrating that the software used with the device was developed under an appropriate software development program.

B. Results

The in vitro and animal studies provided evidence to support the conclusion that the device did not present an unreasonable risk to subjects and could proceed to clinical trials under approved investigational device exemption (IDE) G940119.

IX. SUMMARY OF CLINICAL STUDIES

A. Objectives

The objective of the study was to demonstrate the safety and effectiveness of the Bausch & Lomb Surgical TECHNOLAS®217A Excimer Laser System for the correction of low myopia from –1.00 to –7.00 D with astigmatism of up to -3.00 D when used as part of the LASIK surgical procedure.

B. Study Design

The core study for this submission was a prospective, open-label, non-randomized, multi-center clinical evaluation conducted at three clinical sites in Canada. This evaluation was performed under a protocol submitted to FDA and in accordance with FDA requirements for studies conducted outside the United States, including obtaining written informed consent from each participant. The study protocol required the enrollment of at least 360 eyes in order to achieve the targeted completion of 300 eyes.

1. Inclusion and Exclusion Criteria

In order to be enrolled in the study, patients needed to meet these conditions: have the required amount of myopia and astigmatism; have a stable refraction for the past year; discontinue use of contact lenses prior to surgery; have normal, healthy eyes with visual acuity correctable to at least 20/40; be at least 21 years of age; be willing and able to return for scheduled follow-up examinations; provide written informed consent.

Patients not meeting the above inclusion criteria were excluded from the study. In addition, subjects who exhibited any of the following conditions were excluded: history of anterior segment pathology, including cataracts; residual, recurrent, active ocular or uncontrolled eyelid disease, or any corneal abnormality (specifically, recurrent corneal erosion, severe basement membrane disease); ophthalmoscopic signs of progressive or unstable myopia or keratoconus; required ablation is deeper than 250 microns from the corneal endothelium; unstable corneal mires on central keratotomy readings; blind in fellow eye; previous ocular surgery; history of herpes zoster or herpes simplex keratitis, diabetes, autoimmune disease, connective tissue disease, or clinically significant atopic syndrome; taking chronic systemic corticosteroid or other immunosuppressive therapy; immunocompromised; pregnant, lactating, or of child-bearing potential and not practicing a medically approved form of birth control; sensitivity to planned evaluation medications.

2. Study Endpoints

The following primary study parameters were evaluated in the determination of safety and effectiveness of the TECHNOLAS®217A Excimer Laser System.

Safety Parameters:

- preservation of best-spectacle corrected visual acuity: no more than 5% of eyes should lose two or more lines of BSCVA and less than 1% of eyes with preoperative BSCVA of 20/20 or better should have an outcome worse than 20/25 BSCVA at 3 months or later
- mean extent of induced astigmatism: less than 5% of eyes should have manifest refractive astigmatism that varies from baseline amount by greater than 2.00 D at 3 months or later
- results of slit lamp examination: less than 1% of eyes should have clinically significant haze (that results in a decrease in BSCVA of > 2 lines, not due to irregular astigmatism) at 3 months or later
- cumulative incidence of complications and adverse events (adverse events should occur in less than 5% of eyes)

Effectiveness Parameters:

- predictability: 75% of eyes should have a manifest spherical refraction within ± 1.00 D and 50% should have a manifest spherical refraction within ± 0.50 D of attempted spherical correction at 3 months or later after the primary LASIK surgery
- stability: 95% of eyes should have a change of ≤ 1.00 D in manifest spherical refraction between two refractions performed at least one month apart
- uncorrected visual acuity: 85% of eyes, not corrected for monovision, should have an uncorrected distance visual acuity of 20/40 or better at 3 months or later
- change in manifest refractive astigmatism: 75% of eyes should be within 1.00 D of attempted astigmatism correction at 3 months or later
- patient satisfaction as measured by subjective questionnaire

C. Gender Bias

Regarding any gender bias in the study, the ratio of 54.1% female/45.9% male was evaluated and determined to be reflective of the underlying distribution of myopia and astigmatism in the general population. Furthermore, this distribution of females and males is reflective of the relative ratio of patients in the general population who wear contact lenses

to correct their refractive errors (more females than males are contact lens wearers).

The primary effectiveness and safety outcomes were also examined to determine if gender of the subjects resulted in any differences between the two sexes for the primary effectiveness and safety outcomes. This evaluation revealed no notable differences in the primary outcomes based on gender.

D. Patient Assessments

- Refraction was measured using a standard phoropter.
- Visual acuity was measured using ETDRS charts (Early Treatment of Diabetic Retinopathy Study, National Eye Institute).
- Haze was measured using a slit lamp (biomicroscope).
- Complications and adverse events were measured using all of the above devices and were reported in the case report forms.
- Patient satisfaction was measured using a subjective questionnaire.

E. Accountability

Accountability for all treated eyes across the study visit schedule is presented in Table 1. Additionally, accountability for eyes treated for spherical myopia only and for astigmatic myopia is presented in Tables 2 and 3. There are 367 eyes available for analysis at 1 month, 377 at 3 months and 361 at 6 months. Out of 377 eyes available for analysis at 3 months, 272 were treated for astigmatic myopia and 105 for spherical myopia. At 6 months, there are 266 astigmatic and 95 spherically treated eyes available for analysis.

The first patient was enrolled on December 9, 1998 and the last subject was treated on February 26, 1999. The last subject was exited from the study in August 1999.

F. Demographics

Demographic data for all treated eyes grouped by treatment type are presented in Table 4. The distribution of male and female subjects in the study was approximately even. Racial distribution of the enrolled patients was predominantly white, reflecting the patient population primarily found in both the Ontario and Quebec provinces of Canada. Since nearly every subject enrolled in the study was given a bilateral treatment, the distribution of left and right eyes is virtually equal. The mean age (late 30s) of the subjects for all treated eyes mirrors the data from other excimer laser studies, reflecting the ability of patients to afford excimer laser surgery as an elective procedure.

G. Baseline Refractive Parameters

Presented in Table 5 are the preoperative refraction parameters for those eyes treated for spherical myopia only, while Table 6 presents the preoperative refraction parameters for those eyes treated for astigmatic myopia. The ratio of eyes treated for astigmatic myopia to those treated for spherical myopia only is approximately 3:1, reflecting the general clinical presentation of patients with myopic refractive errors.

H. Stability

Table 7 presents the results for the stability of the manifest refraction spherical equivalent for the consistent cohort (eyes examined at 1, 3, and 6 months). Table 7 demonstrates that over 99% of the overall cohort were within $\pm$ 1 D by 3 months. Mean of the differences was 0.111 D between 1 and 3 months and decreased even further to 0.037 D between 3 and 6 months. Stability analyses stratified by spherical and astigmatic treatment are also indicative of stability at 3 months.

Table 8 presents stability analysis of all treated eyes that had two consecutive exams (pairwise sequential visits). Table 8 (pairwise sequential visits) further supports 3 months as the appropriate endpoint for this study. It is evident from either analysis that refractive stability is achieved in the interval from 1 to 3 months based upon the 95% confidence interval for the percent of eyes within 1.00 D of the previous visit's spherical refraction value.

H. Safety

The key safety variables for all treated eyes at 3 and 6 months are presented in Table 9. These are stratified across all treated eyes, eyes treated for spherical myopia only, and eyes treated for astigmatic myopia. The respective recommended outcomes percentages from the FDA guidance document are also provided for reference.

Safety outcomes stratified by treatment (i.e. spherical vs. astigmatic) do not raise any additional concerns.

1. Best Spectacle Corrected Visual Acuity

At 3 or more months postoperative, 4 cases of loss of BSCVA of at least 2 lines were reported. There were no cases of eyes reported with more than 2 lines of BSCVA loss at 3 or more months postoperative.

For the 4 eyes that lost 2 lines of BSCVA at 3 or more months postoperative, the first case had no significant clinical findings at any postoperative visit, but the BSCVA decreased to 20/20 at all follow-up visits compared to a baseline of 20/12.5. Despite the decreased acuity,

the patient reported being very satisfied with the surgery and would choose to have it again. The second case was the fellow eye of this same patient, and the findings were virtually identical in this eye, with a 2-line decrease at all postoperative visits through Month 6, but no other sequelae.

The third case had a decrease of 2 lines BSCVA from baseline to 20/20 at the Month 3 visit, but with the exception of a mild hyoperopic refraction, there were no other clinical findings reported. At the Month 6 visit, the hyperopia had decreased somewhat, but the BSCVA was still 20/20.

In the fourth case, at the Month 3 visit the BSCVA had decreased to 20/25 from a baseline of 20/16, with no notable clinical findings and only a small residual astigmatism. By the next visit at 6 months, the BSCVA had improved by 3 lines compared to the month 3 visit and by one line compared to baseline to 20/12.5, and all other findings were normal.

None of these BSCVA loss cases represent major concern for the subject device.

2. **Adverse Events and Complications**

Table 10 provides a listing of all adverse events reported during the study at each visit period along with the overall cumulative adverse event rate. The cumulative adverse event rate for all reported events was quite low, with no category of event exceeding 0.8% on a cumulative basis. Virtually all of these adverse events occurred in the immediate postoperative period (Day 1).

For all postoperative visits the following were reported: one case of a corneal abrasion; one case of corneal edema (bed) at > 1 month; 2 cases of folds in flap; 3 cases of misplaced, misaligned, loose flap, or free cap with loss of > 2 lines of BSCVA; 3 cases of procedure aborted; 2 cases of secondary surgical intervention other than excimer laser treatment; and 3 cases of thin flap.

Except for the three cases of aborted procedure, all these cases had UCVA of 20/25 or better at the last postoperative visit.

There were a total of 9 cases of problems during surgery. Among them were 3 eyes for which laser ablation was not attempted due to improper creation of the corneal flap (2 thin flaps, one button-hole flap). The other six eyes with problems during surgery all had UCVA of 20/20 or better at 6 months postoperative.

For all eyes experiencing problems during surgery the problems appear to be typical for this kind of a device.

Table 11 presents a summary of all complications reported for all treated eyes during the course of the study. The incidence rate for all reported categories was quite low, and at the 3- month visit the only complications reported were related to double vision, epithelium in the interface, folds in the flap, haze, peripheral epithelial defect on the flap, and striae in the flap. Only epithelium in the interface (2.9%) and striae in the flap (3.2%) exceeded a 1% incidence rate. At 6 months, the only complications reported were epithelial ingrowth, epithelium in the interface, folds in the flap, overcorrection, and undercorrection. Except for epithelium in the interface (1.1%), none of these exceeded an incidence rate of 1%.

Only epithelium in the interface and striae in the flap were reported to have increased from 1 month to 3 months. For epithelium in the interface, there were an additional 3 eyes (total, 2.9%) reported with this finding compared to 2.2% at the 1-month visit, which is not a clinically significant increase. It is possible that some cells trapped in the interface at one month were not visible due to their small numbers, but proliferated sufficiently to be visible at 3 months. However, at 6 months, only 4 eyes (0.9%) were reported with epithelium in the interface, and none of these eyes had a change in their BSCVA compared to baseline. For striae in the flap, this is believed to be due to direct mechanical manipulation (rubbing, eyelid pressure) of the eye over time which can cause minute displacement or wrinkling of the flap, which is seen as striae on slit lamp examination. This is not considered to be a direct result of the laser treatment.

The nature of adverse events and complications reported in this study are typical for LASIK studies. Furthermore, the rates of adverse events and complications are in the acceptable range.

3. Patient Symptoms

Table 12 provides all patient symptoms for all treated eyes both preoperatively and at 6 months. Symptoms are grouped by severity grade level into "none," "mild," and "≥ moderate" (which includes "moderate," "marked," and "severe"). Symptoms in the mild category are not considered to be clinically significant. It can be seen that those symptoms reported at 6 months postoperatively fall predominantly into the mild category. Those symptoms that were reported at a severity of "moderate" or worse and that occurred at a rate higher than at baseline were halos (3.4% vs. 2.6%), ghost images (0.6% vs. 0%), and variation of vision in normal light (2.0% vs. 1.0%).

For the following symptoms, outcomes at 3 months were somewhat worse in the ≥ moderate category as compared to 6 months: dryness, tearing, halos, fluctuations in vision, variation of vision in bright light and night driving vision. However, overall the increase in patient symptoms associated with this device does not appear to represent a major safety concern.

Table 13 presents the changes in patient symptoms from baseline for all treated eyes at 3 and 6 months postoperative. Those categories in which there was a clinically significantly greater percentage (≥ 5% difference) of eyes reporting that symptoms were worse rather than better include halos and fluctuations of vision.

Besides halos and fluctuations of vision, the following symptoms were reported to be worse than pre-operatively: night driving vision, variation of vision in dim light, blurred vision, glare, gritty feeling, dryness and light sensitivity.

At 3 months, a greater percentage of patients experienced worsening of their symptoms than at 6 months.

Sponsor has also provided patient symptoms stratified by treatment (see Table 14 and 15). Patient symptoms for spherical treatment are of the same order of magnitude as the astigmatic treatment. Thus, patient symptoms for the overall cohort are representative for both groups.

J. Efficacy

Table 16 presents the key effectiveness variables outcomes for all treated eyes at 3 and 6 months.

All the key efficacy outcomes were above the suggested minimum FDA guidance values. In addition, the percent of eyes with 20/20 or better UCVA was 84.8% of all treated eyes at 3 months and 87.3% at 6 months.

The sponsor presented key safety and efficacy outcomes stratified by treatment received (spherical vs. astigmatic). These outcomes are presented in Tables 17 and 18.

Overall outcomes appear to be very good for spherical as well as astigmatic treatment.

The sponsor has also presented key safety and efficacy outcomes stratified by each diopter of preoperative sphere.

The sponsor submitted these with stratification by MRSE (see Tables 19, 20 and 21). Safety and efficacy data for the overall cohort stratified in one diopter increments of preoperative MRSE meet and in most circumstances

exceed the outcomes recommended in the FDA guidance. This holds true for data stratified by treatment (spherical and astigmatic) with one exception of astigmatic myopes with preoperative MRSE > 7.0 D. This group had 44.9% of the eyes (vs. recommended 50%) achieve MRSE within $\pm$ 0.50 D and 11.1% (one eye) of this group experienced loss of $\geq$ 2 lines of BSCVA.

Overall, data stratified by preoperative MRSE do not raise any additional safety or efficacy concerns.

1. Cylinder Correction

Presented in Table 22 is the residual astigmatic error at 3 and 6 months postoperative for eyes that were treated for astigmatic myopia. It can be seen that 96.0% and 94.7% of eyes had a residual cylinder of less than 1.0 D at 3 and 6 months, respectively.

Table 22 also reveals that at 3 months, there were only 4 eyes with residual cylinder magnitude >1.00 D that had absolute shift in manifest axis >30°.

Table 23 reveals the same information stratified by each preoperative diopter of absolute cylinder. This table reveals that for each diopter up to 2.99 D, about 40% of eyes ended up with absolute shift in manifest axis > 30 degrees. Among the eyes with absolute shift in manifest axis > 30 degrees, only a small percentage of eyes had residual manifest cylinder magnitude of $\geq$1.00 D. Thus, it does not represent a major safety concern.

For preoperative manifest cylinder 1.00 to 1.99 D, 10.1% of eyes had residual cylinder $\geq$ 1.0 D. For preoperative cylinder 2.00 to 2.99 D, this percentage decreases to 2.9%. For preoperative cylinder range of 3.00 to 3.99 D, however, the percentage of eyes with residual cylinder $\geq$ 1.0 D jumps to 20%. This could be an artifact of a very low N (5).

Table 24 presents the results for the FDA-recommended vector magnitude analysis of the cylinder correction at 3 and 6 months postoperative for all eyes treated for astigmatic myopia that had complete preoperative and 3 or 6 months postoperative refraction data (N = 272 at 3 months and 266 at 6 months). The mean surgically induced residual cylinder/induced residual cylinder (SIRC/IRC) ratio indicates that the cylinder treatments were, on average, virtually the same as the intended correction (a ratio of 1.00 indicates that the IRC and the SIRC were the same).

Table 24 reveals an SIRC/IRC ratio of 0.99 at 3 and 6 months.

Table 25 presents stratification by diopter of preoperative cylinder percent reduction of absolute cylinder and achieved vs intended vector magnitude ratio. At 3 months, percent reduction of absolute cylinder is lowest at 62.5% for eyes with preoperative cylinder < 1.0D. This is consistent with the expectations for this range. Best performance is seen for eyes with preoperative cylinder in the 2.00 to 2.99D range (87.7% mean reduction in absolute cylinder and 0.97 SIRC/IRC).

For the 5 eyes in the 3.00 to 3.99 eyes preoperative cylinder range, SIRC/IRC is 0.86 (a significant decrease from 0.97 seen in the 2.00 to 2.99D range) . This is most likely due to small number of eyes in this range, especially in light of the fact that by 6 months the difference becomes rather small (0.98 vs. 0.95).

Overall the in the PMA demonstrates the effectiveness of the device in the correction of preoperative cylinder correction up to 2.99 D.

2. Effect of Baseline Factors on Post-Treatment

Gender, preoperative refraction, age, and study site were evaluated as predictors of the UCVA and refractive outcome for the LASIK procedure. Table 26 summarizes the Generalized Estimating Equation (GEE) modeling results.

These analyses show the following:

a) The success rates at 6 months seem higher than those at 3 months. However, the differences are not clinically significant.
b) At 6 months, the percentage for vector deviation ≤ 0.50 D is lower for the female group than for the male group (74.5% vs. 85.1%). However, for vector deviation ≤ 1.00 D, this difference narrows somewhat (86.2% for females vs. 92.6% for males).
c) The effect of age on the success rate of UCVA 20/40 or better is not clinically significant. The age group of "50 to <60" seems to have a relatively lower percentage of eyes with a MRSPH deviation from attempted correction within ±0.50 D. The percentages are 53.5% at 3 months and 64.3% at 6 months. However, both of these values are higher than the recommended FDA guidance value of 50%.
d) Although there is a difference among the study sites in the success rate of MRSPH deviation from attempted correction within ±0.50 D, the rates are all higher than the recommended FDA guidance values. There is no clinical site effect on the success rate of MRSPH deviation from attempted correction within ±1.00 D.
e) Eyes with a preoperative cylinder of 0.00 to 0.99 D have a somewhat lower percentage for vector deviation ≤ 1.00D (79.2% at

3 months and 82.9% at 6 months). The reason for this is that the protocol permitted eyes with these lower amounts of astigmatism to be treated for the astigmatic myopia. As a result, postoperatively these eyes could have a resulting vector deviation from intended correction ≤ 1.00D, but the remaining astigmatism could still be equal to the preoperative astigmatism, and hence were not counted as a successful event.

3. Subjective Self-evaluation

Responses provided by the study subjects at 3 months to three questions regarding their experiences with the laser surgery are provided in Table 27. These three questions related to: 1) the perceived overall quality of vision following the surgery; 2) the subject's willingness to have the surgery again if he/she could make the choice over; and, 3) the subject's overall satisfaction with the results of the surgical procedure.

The overall quality of vision was rated highly, with 96.2% of patients (by eye) indicating that there was an extreme or marked improvement, while only 0.3% indicated that there was only slight or no improvement; 98.4% would elect to have the surgery again; 91.0% reported being very satisfied and 7.6% reported being moderately satisfied, while only 0.3% of eyes reported being dissatisfied; and, no cases reported being very dissatisfied.

Comparing the outcomes of spherical and astigmatic treatment groups, reveal no great discrepancies between these groups.

K. Device Failures and Replacements

There were three device failures/malfunctions and there were no device replacements during the course of the study. The three failures were aborted surgeries due to poor corneal flap creation with the microkeratome.

X. CONCLUSIONS DRAWN FROM THE STUDIES

The data in this application provides reasonable assurance that the device is safe and effective when used in accordance with the directions for use.

XI. PANEL RECOMMENDATION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

CDRH issued an approval order on February 23, 2000. The applicant's manufacturing facility was inspected on May 5 – 8, 1998 and was found to be in compliance with the device Quality System Regulation.

XIII. APPROVAL SPECIFICATIONS

Directions for Use: See Device Labeling.

Hazards to health from use of the device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling

Post approval requirements and restrictions: See Approval Order

Attachments – Tables 1 through 27

Table 1: Accountability - All Treated Eyes

Status		1 Month	3 Months	6 Months
Available for Analysis	n/N (%)	367/386 (95.1%)	377/386 (97.7%)	361/386 (93.5%)
Discontinued*	n/N (%)	3/386 (0.8%)	3/386 (0.8%)	5/386 (1.3%)
Active (Not yet eligible for the interval)	n/N (%)	0/386 (0.0%)	0/386 (0.0%)	0/386 (0.0%)
Lost to Follow-up†	n/N (%)	4/386 1.0%)	6/386 1.6%)	20/386 (5.2%)
Missed Visit‡	n/N (%)	12/386 (3.1%)	0/386 (0.0%)	0/386 (0.0%)
% Accountability = Available for Analysis ÷ (Enrolled - Discontinued - Not yet eligible)		367/383 (95.8%)	377/383 (98.4%)	361/381 (94.8%)

N = Total eyes enrolled

* Discontinued = Exited due to Technolas laser retreatment (2 eyes) or non-Technolas laser retreatment (0 eye) or aborted procedure (3 eyes) or death (0 eye).

† Loss to follow-up: Eyes not examined at the scheduled or subsequent visits, and not considered active or discontinued. 20 cases of lost-to-follow-up were 308-8023-A0, 308-8023-B0, 308-8028-A0, 308-8028-B0, 320-8030-A0, 320-8030-B0, 335-8017-A0, 335-8017-B0, 335-8020-A0, 335-8020-B0, 401-8014-A0, 401-8014-B0, 401-8022-A0, 401-8022-B0, 403-8034-A0, 403-8034-B0, 403-8043-A0, 403-8043-B0, 403-8050-A0, and 403-8050-B0.

‡ Missed visit: Eyes not examined at the scheduled visit, but were then seen at a subsequent visit.

Table 2: Accountability - Eyes Treated for Spherical Myopia Only

Status		1 Month	3 Months	6 Months
Available for Analysis	n/N (%)	103/110 (93.6%)	105/110 (95.5%)	95/110 (86.4%)
Discontinued*	n/N (%)	2/110 (1.8%)	2/110 (1.8%)	2/110 (1.8%)
Active (Not yet eligible for the interval)	n/N (%)	0/110 (0.0%)	0/110 (0.0%)	0/110 (0.0%)
Lost to Follow-up†	n/N (%)	3/110 (2.7%)	3/110 (2.7%)	13/110 (11.8%)
Missed Visit‡	n/N (%)	2/110 (1.8%)	0/110 (0.0%)	0/110 (0.0%)
% Accountability = Available for Analysis ÷ (Enrolled - Discontinued - Not yet eligible)		103/108 (95.4%)	105/108 (97.2%)	95/108 (88.0%)

N = Total eyes enrolled

* Discontinued = Exited due to Technolas laser retreatment (0 eye) or non-Technolas laser retreatment (0 eye) or aborted procedure (2 eyes) or death (0 eye).

† Loss to follow-up: Eyes not examined at the scheduled or subsequent visits, and not considered active or discontinued. 13 cases of lost-to-follow-up were 308-8023-A0, 308-8023-B0, 308-8028-A0, 308-8028-B0, 320-8030-A0, 320-8030-B0, 401-8014-A0, 401-8022-A0, 401-8022-B0, 403-8043-A0, 403-8043-B0, 403-8050-A0, and 403-8050-B0.

‡ Missed visit: Eyes not examined at the scheduled visit, but were then seen at a subsequent visit.

Table 4: Demographics - All Treated Eyes

Demographics	Treated for Spherical Myopia Only		Treated for Astigmatic Myopia		All Treated Eyes	
	Number	Percentage	Number	Percentage	Number	Percentage
NUMBER OF EYES & SUBJECTS	110 Eyes of 75 Enrolled Subjects		276 Eyes of 159 Enrolled Subjects		386 Eyes of 196 Enrolled Subjects	
GENDER						
Male	52	47.3%	125	45.3%	177	45.9%
Female	58	52.7%	151	54.7%	209	54.1%
RACE						
White	107	97.3%	263	95.3%	370	95.9%
Black	0	0.0%	4	1.4%	4	1.0%
Asian	2	1.8%	6	2.2%	8	2.1%
Other	1	0.9%	3	1.1%	4	1.0%
SURGICAL EYE						
Right	56	50.9%	137	49.6%	193	50.0%
Left	54	49.1%	139	50.4%	193	50.0%
AGE (in years)						
Mean	36.8 (10.4)		38.3 (9.2)		37.9 (9.6)	
Minimum, Maximum	21, 66		21, 61		21, 66	

Table 5: Preoperative Refraction Parameters - Eyes Treated for Spherical Myopia

Manifest Refraction	Primary Eyes Number	%	Fellow Eyes Number	%	Total Eyes Number	%
Sphere						
1.00-1.99 D	5	9.1	4	7.3	9	8.2
2.00-2.99 D	15	27.3	14	25.5	29	26.4
3.00-3.99 D	8	14.5	9	16.4	17	15.5
4.00-4.99 D	10	18.2	12	21.8	22	20.0
5.00-5.99 D	13	23.6	8	14.5	21	19.1
6.00-7.00 D	4	7.3	8	14.5	12	10.9
Mean (SD)	*3.81 (1.49)*		*3.91 (1.57)*		*3.86 (1.52)*	
Range	*1.25 to 6.50*		*1.00 to 7.00*		*1.00 to 7.00*	
Total	55	100.0	55	100.0	110	100.0
Cylinder						
0.00 D	44	80.0	38	69.1	82	74.5
0.25 D	10	18.2	15	27.3	25	22.7
0.50 D	1	1.8	1	1.8	2	1.8
0.75 D	0	0.0	1	1.8	1	0.9
Mean (SD)	*0.05 (0.11)*		*0.09 (0.15)*		*0.07 (0.14)*	
Range	*0.00 to 0.50*		*0.00 to 0.75*		*0.00 to 0.75*	
Total	55	100.0	55	100.0	110	100.0

2 eyes (-5.55D sphere, -2.75D sphere) were reported with an aborted procedure.
3 of 15 eyes that were treated for mono-vision had a spherical myopia treatment only.

Table 6: Preoperative Refraction Parameters - Eyes Treated for Astigmatic Myopia

Stratified by Sphere and Cylinder Components

Manifest Sphere Mean (SD): 3.59 (1.42) Range: 1.00 to 7.00	Manifest Cylinder Mean (SD): 1.07 (0.66), Range: 0.25 to 3.50				Total
	0.00 to 0.99 D n/N (%)	1.00 to 1.99 D N/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	n/N (%)
1.00 to 1.99 D	20/276 (7.2)	8/276 (2.9)	4/276 (1.4)	1/276 (0.4)	33/276 (12.0)
2.00 to 2.99 D	29/276 (10.5)	23/276 (8.3)	6/276 (2.2)	1/276 (0.4)	59/276 (21.4)
3.00 to 3.99 D	41/276 (14.9)	30/276 (10.9)	7/276 (2.5)	2/276 (0.7)	80/276 (29.0)
4.00 to 4.99 D	31/276 (11.2)	11/276 (4.0)	6/276 (2.2)	1/276 (0.4)	49/276 (17.8)
5.00 to 5.99 D	13/276 (4.7)	10/276 (3.6)	5/276 (1.8)	0/276 (0.0)	28/276 (10.1)
6.00 to 7.00 D	12/276 (4.3)	9/276 (3.3)	6/276 (2.2)	0/276 (0.0)	27/276 (9.8)
Total	146/276 (52.9)	91/276 (33.0)	34/276 (12.3)	5/276 (1.8)	276/276 (100.0)

N = Total number of eyes treated for astigmatic myopia.

1 eye (-2.75-0.75x175) was reported with an aborted procedure.

12 of 15 eyes that were treated for mono-vision had an astigmatic myopia treatment.

Table 7: Stability of Manifest Spherical Equivalent - Consistent Cohort

Change Between Consecutive Visits	Between 1 and 3 Months			Between 3 and 6 Months		
	Full Cohort n/N (%)	Eyes Treated for Spherical Myopia Only n/N (%)	Eyes Treated for Astigmatic Myopia n/N (%)	Full Cohort n/N (%)	Eyes Treated for Spherical Myopia Only n/N (%)	Eyes Treated for Astigmatic Myopia n/N (%)
> 3.00 D	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)
2.01 to 3.00 D	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)
1.01 to 2.00 D	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)	1/349 (0.3%)	1/93 (1.1%)	0/256 (0.0%)
-1.00 to 1.00 D	**348/349 (99.7%)**	**93/93 (100.0%)**	**255/256 (99.6%)**	**346/349 (99.1%)**	**91/93 (97.8%)**	**255/256 (99.6%)**
(-0.50 to 0.50 D)	306/349 (87.7%)	85/93 (91.4%)	221/256 (86.3%)	331/349 (94.8%)	88/93 (94.6%)	243/256 (94.9%)
-2.00 to -1.01 D	1/349 (0.3%)	0/93 (0.0%)	1/256 (0.4%)	2/349 (0.6%)	1/93 (1.1%)	1/256 (0.4%)
-3.00 to -2.01 D	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)
< -3.00 D	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)	0/349 (0.0%)	0/93 (0.0%)	0/256 (0.0%)
95% CI for % of within 1.00 D	***(98.8, 99.9)***	***(96.4, 100.0)***	***(98.3, 99.9)***	***(98.0, 99.9)***	***(94.3, 99.9)***	***(98.3, 99.9)***
95% CI for % of within 0.50 D	***(83.7, 91.7)***	***(85.1, 97.7)***	***(81.5, 91.2)***	***(92.2, 97.5)***	***(90.1, 99.2)***	***(91.7, 98.2)***
Mean (SD)	**-0.111 (0.340)**	**-0.050 (0.322)**	**-0.134 (0.344)**	**-0.037 (0.297)**	**-0.047 (0.307)**	**-0.034 (0.292)**
95% CI for Mean	***(-0.155, -0.068)***	***(-0.126, 0.027)***	***(-0.184, -0.084)***	***(-0.075, 0.000)***	***(-0.116, 0.022)***	***(-0.077, 0.010)***
Range	-1.250 to 1.000	-1.000 to 0.625	-1.250 to 1.000	-1.250 to 1.250	-1.250 to 1.250	-1.250 to 1.000
Not reported†	0	0	0	0	0	0
Total‡	349	93	256	349	93	256

N = Number of CRFs received with non-missing values at each visit.

The 95% confidence interval was adjusted for the correlation between eyes.

* All eyes examined at 1, 3, and 6 months.

† Number of CRFs received with missing values at each visit.

‡ Number of CRFs received at each visit.

Table 8: Stability of Manifest Spherical Equivalent - Pairwise Sequential Visits

Change Between Consecutive Visits	Between 1 and 3 Months			Between 3 and 6 Months		
	Full Cohort n/N (%)	Eyes Treated for Spherical Myopia Only n/N (%)	Eyes Treated for Astigmatic Myopia n/N (%)	Full Cohort n/N (%)	Eyes Treated for Spherical Myopia Only n/N (%)	Eyes Treated for Astigmatic Myopia n/N (%)
> 3.00 D	0/365 (0.0%)	0/103 (0.0%)	0/262 (0.0%)	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)
2.01 to 3.00 D	0/365 (0.0%)	0/103 (0.0%)	0/262 (0.0%)	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)
1.01 to 2.00 D	0/365 (0.0%)	0/103 (0.0%)	0/262 (0.0%)	1/361 (0.3%)	1/95 (1.1%)	0/266 (0.0%)
-1.00 to 1.00 D	**364/365 (99.7%)**	**103/103 (100.0%)**	**261/262 (99.6%)**	**358/361 (99.2%)**	**93/95 (97.9%)**	**265/266 (99.6%)**
(-0.50 to 0.50 D)	322/365 (88.2%)	95/103 (92.2%)	227/262 (86.6%)	342/361 (94.7%)	90/95 (94.7%)	252/266 (94.7%)
-2.00 to -1.01 D	1/365 (0.3%)	0/103 (0.0%)	1/262 (0.4%)	2/361 (0.6%)	1/95 (1.1%)	1/266 (0.4%)
-3.00 to -2.01 D	0/365 (0.0%)	0/103 (0.0%)	0/262 (0.0%)	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)
< -3.00 D	0/365 (0.0%)	0/103 (0.0%)	0/262 (0.0%)	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)
95% CI for % of within 1.00 D	***(98.8, 99.9)***	***(96.8, 100.0)***	***(98.3, 99.9)***	***(98.1, 99.9)***	***(94.4, 99.9)***	***(98.4, 99.9)***
95% CI for % of within 0.50 D	***(84.4, 92.0)***	***(86.5, 98.0)***	***(81.9, 91.4)***	***(92.1, 97.3)***	***(90.3, 99.2)***	***(91.6, 97.9)***
Mean (SD)	**-0.115 (0.337)**	**-0.069 (0.322)**	**-0.133 (0.341)**	**-0.039 (0.294)**	**-0.049 (0.304)**	**-0.036 (0.290)**
95% CI for Mean	***(-0.158, -0.073)***	***(-0.144, 0.005)***	***(-0.182, -0.084)***	***(-0.076, -0.002)***	***(-0.116, 0.019)***	***(-0.078, 0.007)***
Range	-1.250 to 1.000	-1.000 to 0.625	-1.250 to 1.000	-1.250 to 1.250	-1.250 to 1.250	-1.250 to 1.000
Not reported†	12	2	10	0	0	0
Total‡	377	105	272	361	95	266

N = Number of CRFs received with non-missing values at each visit.

The 95% confidence interval was adjusted for the correlation between eyes.

* Eyes that had two consecutive exams, but not necessarily every follow-up exam.

† Number of CRFs received with missing values at each visit.

‡ Number of CRFs received at each visit.

Table 9: Key Safety Variables at 3 And 6 Months - All Treated Eyes

Key Safety Events	All Eyes n/N (%)	Spherical Myopia n/N (%)	Astigmatic Myopia n/N (%)	FDA 1996 Guidance
3 Months				
Loss of ≥ 2 lines BSCVA	4/376 (1.1%)	2/105 (1.9%)	2/271 (0.7%)	NA
Loss of > 2 lines BSCVA	0/376 (0.0%)	0/105 (0.0%)	0/271 (0.0%)	< 5%
BSCVA worse than 20/40	0/376 (0.0%)	0/105 (0.0%)	0/271 (0.0%)	< 1%
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/362 (0.0%)	0/103 (0.0%)	0/259 (0.0%)	NA
Haze ≥ trace with loss of BSCVA > 2 lines	0/376 (0.0%)	0/105 (0.0%)	0/271 (0.0%)	NA
Increased manifest refractive astigmatism > 2.0 D*	0/105 (0.0%)	0/105 (0.0%)	NA	< 5%
6 Months				
Loss of ≥ 2 lines BSCVA	3/361 (0.8%)	2/95 (2.1%)	1/266 (0.4%)	NA
Loss of > 2 lines BSCVA	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)	< 5%
BSCVA worse than 20/40	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)	< 1%
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/347 (0.0%)	0/93 (0.0%)	0/254 (0.0%)	NA
Haze ≥ trace with loss of BSCVA > 2 lines	0/361 (0.0%)	0/95 (0.0%)	0/266 (0.0%)	NA
Increased manifest refractive astigmatism > 2.0 D*	0/95 (0.0%)	0/95 (0.0%)	NA	< 5%

N = Number of CRFs received with non-missing values at each visit.

* For eyes treated with spherical myopia only.

Table 10: Adverse Events Summary - All Treated Eyes

All Reported Adverse Events	1 Day N/N (%)	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	Cumulative n/N (%)
Corneal abrasion	0/386 (0.0%)	0/367 (0.0%)	0/377 (0.0%)	1/361 (0.3%)	1/386 (0.3%)
Corneal edema (bed) at > 1 month	0/386 (0.0%)	0/367 (0.0%)	1/377 (0.3%)	0/361 (0.0%)	1/386 (0.3%)
Folds in flap	1/386 (0.3%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)	2/386 (0.5%)
Misplaced, misaligned, loose flap, or free cap with loss of > 2 lines of BSCVA	3/386 (0.8%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)	3/386 (0.8%)
Procedure aborted	0/386 (0.0%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)	3/386 (0.8%)
Secondary surgical intervention other than excimer laser treatment	2/386 (0.5%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)	2/386 (0.5%)
Thin flap	2/386 (0.5%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)	3/386 (0.8%)
Not reported*	0	0	0	0	0
Total†	386	367	377	361	386

1 FOLDS IN FLAP, 3 PROCEDURE ABORTED, & 3 THIN FLAP were reported at surgery day.

N = Number of CRFs received with non-missing values at each visit.

The maximal cumulative adverse event rate is 0.8%.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.

Table 11: Complications Summary - All Treated Eyes

All Reported Complications	1 Day n/N (%)	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Corneal edema at ≤ 1 month	18/386 (4.7%)	2/367 (0.5%)	0/377 (0.0%)	0/361 (0.0%)
Corneal scarring	0/386 (0.0%)	1/367 (0.3%)	0/377 (0.0%)	0/361 (0.0%)
Double vision	0/386 (0.0%)	1/367 (0.3%)	1/377 (0.3%)	0/361 (0.0%)
Epithelial ingrowth	0/386 (0.0%)	0/367 (0.0%)	0/377 (0.0%)	1/361 (0.3%)
Epithelium in the interface with loss ≤ 2 lines of BSCVA	4/386 (1.0%)	8/367 (2.2%)	11/377 (2.9%)	4/361 (1.1%)
Folds in flap	2/386 (0.5%)	17/367 (4.6%)	1/377 (0.3%)	2/361 (0.6%)
Haze	0/386 (0.0%)	1/367 (0.3%)	1/377 (0.3%)	0/361 (0.0%)
Lamellar keratitis	1/386 (0.3%)	1/367 (0.3%)	0/377 (0.0%)	0/361 (0.0%)
Overcorrection	0/386 (0.0%)	0/367 (0.0%)	0/377 (0.0%)	1/361 (0.3%)
Peripheral corneal epithelial defect (on the flap)	3/386 (0.8%)	0/367 (0.0%)	1/377 (0.3%)	0/361 (0.0%)
Size and shape of flap not as intended	1/386 (0.3%)	0/367 (0.0%)	0/377 (0.0%)	0/361 (0.0%)
Striae in flap	0/386 (0.0%)	2/367 (0.5%)	12/377 (3.2%)	0/361 (0.0%)
Stromal scar	0/386 (0.0%)	1/367 (0.3%)	0/377 (0.0%)	0/361 (0.0%)
Undercorrection	0/386 (0.0%)	0/367 (0.0%)	0/377 (0.0%)	2/361 (0.6%)
Not reported*	0	0	0	0
Total†	386	367	377	361

1 LAMELLAR KERATITIS was reported at an interim visit between 1 day to 1 month postop. 1 HAZE was reported at an interim visit between 1 to 3 months postop.

N = Number of CRFs received with non-missing values at each visit.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.

Table 12: Patient Symptoms at Preop, 3 Months, & 6 Months - All Treated Eyes

Patient Symptoms	None n/N (%)			Mild n/N (%)			≥ Moderate n/N (%)		
	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months
Light sensitivity	273/386 (70.7%)	277/370 (74.9%)	277/348 (79.6%)	67/386 (17.4%)	68/370 (18.4%)	53/348 (15.2%)	46/386 (11.9%)	25/370 (6.8%)	18/348 (5.2%)
Headaches	309/386 (80.1%)	335/370 (90.5%)	326/348 (93.7%)	38/386 (9.8%)	28/370 (7.6%)	16/348 (4.6%)	39/386 (10.1%)	7/370 (1.9%)	6/348 (1.7%)
Pain	361/386 (93.5%)	341/370 (92.2%)	337/348 (96.8%)	19/386 (4.9%)	26/370 (7.0%)	8/348 (2.3%)	6/386 (1.6%)	3/370 (0.8%)	3/348 (0.9%)
Redness	294/386 (76.2%)	311/370 (84.1%)	306/348 (87.9%)	71/386 (18.4%)	54/370 (14.6%)	32/348 (9.2%)	21/386 (5.4%)	5/370 (1.4%)	10/348 (2.9%)
Dryness	236/386 (61.1%)	223/370 (60.3%)	227/348 (65.2%)	86/386 (22.3%)	95/370 (25.7%)	97/348 (27.9%)	64/386 (16.6%)	52/370 (14.1%)	24/348 (6.9%)
Tearing	337/386 (87.3%)	345/370 (93.2%)	328/348 (94.3%)	32/386 (8.3%)	16/370 (4.3%)	15/348 (4.3%)	17/386 (4.4%)	9/370 (2.4%)	5/348 (1.4%)
Burning	332/386 (86.0%)	324/370 (87.6%)	329/348 (94.5%)	48/386 (12.4%)	40/370 (10.8%)	14/348 (4.0%)	6/386 (1.6%)	6/370 (1.6%)	5/348 (1.4%)
Gritty feeling	331/386 (85.8%)	331/370 (89.5%)	320/348 (92.0%)	46/386 (11.9%)	33/370 (8.9%)	27/348 (7.8%)	9/386 (2.3%)	6/370 (1.6%)	1/348 (0.3%)
Glare	332/386 (86.0%)	293/370 (79.2%)	297/348 (85.3%)	38/386 (9.8%)	61/370 (16.5%)	42/348 (12.1%)	16/386 (4.1%)	16/370 (4.3%)	9/348 (2.6%)
Halos	346/386 (89.6%)	257/370 (69.5%)	271/348 (77.9%)	30/386 (7.8%)	86/370 (23.2%)	65/348 (18.7%)	10/386 (2.6%)	27/370 (7.3%)	12/348 (3.4%)
Blurred vision	315/386 (81.6%)	284/370 (76.8%)	294/348 (84.5%)	52/386 (13.5%)	76/370 (20.5%)	47/348 (13.5%)	19/386 (4.9%)	10/370 (2.7%)	7/348 (2.0%)
Double vision	373/386 (96.6%)	358/370 (96.8%)	339/348 (97.4%)	11/386 (2.8%)	9/370 (2.4%)	7/348 (2.0%)	2/386 (0.5%)	3/370 (0.8%)	2/348 (0.6%)
Ghost images	378/386 (97.9%)	359/370 (97.0%)	338/348 (97.1%)	8/386 (2.1%)	7/370 (1.9%)	8/348 (2.3%)	0/386 (0.0%)	4/370 (1.1%)	2/348 (0.6%)
Fluctuations of vision	347/386 (89.9%)	296/370 (80.0%)	285/348 (81.9%)	29/386 (7.5%)	63/370 (17.0%)	55/348 (15.8%)	10/386 (2.6%)	11/370 (3.0%)	8/348 (2.3%)
Variation of vision in bright light	327/386 (84.7%)	325/370 (87.8%)	301/348 (86.5%)	47/386 (12.2%)	32/370 (8.6%)	42/348 (12.1%)	12/386 (3.1%)	13/370 (3.5%)	5/348 (1.4%)
Variation of vision in normal light	366/386 (94.8%)	329/370 (88.9%)	325/348 (93.4%)	16/386 (4.1%)	35/370 (9.5%)	16/348 (4.6%)	4/386 (1.0%)	6/370 (1.6%)	7/348 (2.0%)
Variation of vision in dim light	298/386 (77.2%)	285/370 (77.0%)	278/348 (79.9%)	72/386 (18.7%)	58/370 (15.7%)	56/348 (16.1%)	16/386 (4.1%)	27/370 (7.3%)	14/348 (4.0%)
Night driving vision	272/386 (70.5%)	291/370 (78.6%)	282/348 (81.0%)	87/386 (22.5%)	52/370 (14.1%)	51/348 (14.7%)	27/386 (7.0%)	27/370 (7.3%)	15/348 (4.3%)
Discharge	384/386 (99.5%)	370/370 (100.0%)	348/348 (100.0%)	2/386 (0.5%)	0/370 (0.0%)	0/348 (0.0%)	0/386 (0.0%)	0/370 (0.0%)	0/348 (0.0%)
Edema, lid	384/386 (99.5%)	370/370 (100.0%)	348/348 (100.0%)	2/386 (0.5%)	0/370 (0.0%)	0/348 (0.0%)	0/386 (0.0%)	0/370 (0.0%)	0/348 (0.0%)
Floaters	384/386 (99.5%)	370/370 (100.0%)	348/348 (100.0%)	2/386 (0.5%)	0/370 (0.0%)	0/348 (0.0%)	0/386 (0.0%)	0/370 (0.0%)	0/348 (0.0%)
Itching	386/386 (100.0%)	369/370 (99.7%)	348/348 (100.0%)	0/386 (0.0%)	1/370 (0.3%)	0/348 (0.0%)	0/386 (0.0%)	0/370 (0.0%)	0/348 (0.0%)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

At 3 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

At 6 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

Table 13: Patient Symptoms Change from Baseline - All Treated Eyes

Patient Symptoms	3 Months n/N (%)			6 Months n/N (%)		
	Better	No Change	Worse	Better	No Change	Worse
Light sensitivity	77/370 (20.8)	239/370 (64.6)	**54/370 (14.6)**	80/348 (23.0)	230/348 (66.1)	**38/348 (10.9)**
Headaches	65/370 (17.6)	291/370 (78.6)	**14/370 (3.8)**	63/348 (18.1)	278/348 (79.9)	**7/348 (2.0)**
Pain	16/370 (4.3)	332/370 (89.7)	**22/370 (5.9)**	16/348 (4.6)	325/348 (93.4)	**7/348 (2.0)**
Redness	66/370 (17.8)	272/370 (73.5)	**32/370 (8.6)**	70/348 (20.1)	256/348 (73.6)	**22/348 (6.3)**
Dryness	73/370 (19.7)	221/370 (59.7)	**76/370 (20.5)**	98/348 (28.2)	191/348 (54.9)	**59/348 (17.0)**
Tearing	43/370 (11.6)	312/370 (84.3)	**15/370 (4.1)**	43/348 (12.4)	298/348 (85.6)	**7/348 (2.0)**
Burning	36/370 (9.7)	301/370 (81.4)	**33/370 (8.9)**	42/348 (12.1)	291/348 (83.6)	**15/348 (4.3)**
Gritty feeling	42/370 (11.4)	301/370 (81.4)	**27/370 (7.3)**	45/348 (12.9)	282/348 (81.0)	**21/348 (6.0)**
Glare	39/370 (10.5)	272/370 (73.5)	**59/370 (15.9)**	38/348 (10.9)	274/348 (78.7)	**36/348 (10.3)**
Halos	18/370 (4.9)	259/370 (70.0)	**93/370 (25.1)**	21/348 (6.0)	263/348 (75.6)	**64/348 (18.4)**
Blurred vision	39/370 (10.5)	275/370 (74.3)	**56/370 (15.1)**	50/348 (14.4)	262/348 (75.3)	**36/348 (10.3)**
Double vision	6/370 (1.6)	356/370 (96.2)	**8/370 (2.2)**	10/348 (2.9)	329/348 (94.5)	**9/348 (2.6)**
Ghost images	4/370 (1.1)	357/370 (96.5)	**9/370 (2.4)**	4/348 (1.1)	336/348 (96.6)	**8/348 (2.3)**
Fluctuations of vision	24/370 (6.5)	286/370 (77.3)	**60/370 (16.2)**	26/348 (7.5)	271/348 (77.9)	**51/348 (14.7)**
Variation of vision in bright light	37/370 (10.0)	304/370 (82.2)	**29/370 (7.8)**	31/348 (8.9)	295/348 (84.8)	**22/348 (6.3)**
Variation of vision in normal light	11/370 (3.0)	323/370 (87.3)	**36/370 (9.7)**	14/348 (4.0)	314/348 (90.2)	**20/348 (5.7)**
Variation of vision in dim light	53/370 (14.3)	262/370 (70.8)	**55/370 (14.9)**	60/348 (17.2)	245/348 (70.4)	**43/348 (12.4)**
Night driving vision	75/370 (20.3)	244/370 (65.9)	**51/370 (13.8)**	79/348 (22.7)	229/348 (65.8)	**40/348 (11.5)**
Discharge	2/370 (0.5)	368/370 (99.5)	**0/370 (0.0)**	2/348 (0.6)	346/348 (99.4)	**0/348 (0.0)**
Edema, lid	2/370 (0.5)	368/370 (99.5)	**0/370 (0.0)**	2/348 (0.6)	346/348 (99.4)	**0/348 (0.0)**
Eye strain	0/370 (0.0)	370/370 (100.0)	**0/370 (0.0)**	0/348 (0.0)	348/348 (100.0)	**0/348 (0.0)**
Floaters	2/370 (0.5)	368/370 (99.5)	**0/370 (0.0)**	2/348 (0.6)	346/348 (99.4)	**0/348 (0.0)**
Itching	0/370 (0.0)	369/370 (99.7)	**1/370 (0.3)**	0/348 (0.0)	348/348 (100.0)	**0/348 (0.0)**
Night vision	0/370 (0.0)	370/370 (100.0)	**0/370 (0.0)**	0/348 (0.0)	348/348 (100.0)	**0/348 (0.0)**

Table 14: Patient Symptoms at Preop, 3 Months, & 6 Months - Eyes Treated for Spherical Myopia Only

Patient Symptoms	None n/N (%)			Mild n/N (%)			≥ Moderate n/N (%)		
	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months
Light sensitivity	77/110 (70.0%)	78/104 (75.0%)	70/88 (79.5%)	18/110 (16.4%)	18/104 (17.3%)	11/88 (12.5%)	15/110 (13.6%)	8/104 (7.7%)	7/88 (8.0%)
Headaches	93/110 (84.5%)	96/104 (92.3%)	82/88 (93.2%)	10/110 (9.1%)	6/104 (5.8%)	3/88 (3.4%)	7/110 (6.4%)	2/104 (1.9%)	3/88 (3.4%)
Pain	107/110 (97.3%)	100/104 (96.2%)	87/88 (98.9%)	2/110 (1.8%)	4/104 (3.8%)	1/88 (1.1%)	1/110 (0.9%)	0/104 (0.0%)	0/88 (0.0%)
Redness	87/110 (79.1%)	88/104 (84.6%)	78/88 (88.6%)	19/110 (17.3%)	14/104 (13.5%)	8/88 (9.1%)	4/110 (3.6%)	2/104 (1.9%)	2/88 (2.3%)
Dryness	70/110 (63.6%)	60/104 (57.7%)	47/88 (53.4%)	21/110 (19.1%)	25/104 (24.0%)	31/88 (35.2%)	19/110 (17.3%)	19/104 (18.3%)	10/88 (11.4%)
Tearing	100/110 (90.9%)	96/104 (92.3%)	82/88 (93.2%)	7/110 (6.4%)	4/104 (3.8%)	4/88 (4.5%)	3/110 (2.7%)	4/104 (3.8%)	2/88 (2.3%)
Burning	99/110 (90.0%)	96/104 (92.3%)	84/88 (95.5%)	9/110 (8.2%)	5/104 (4.8%)	2/88 (2.3%)	2/110 (1.8%)	3/104 (2.9%)	2/88 (2.3%)
Gritty feeling	93/110 (84.5%)	92/104 (88.5%)	84/88 (95.5%)	14/110 (12.7%)	9/104 (8.7%)	4/88 (4.5%)	3/110 (2.7%)	3/104 (2.9%)	0/88 (0.0%)
Glare	95/110 (86.4%)	81/104 (77.9%)	72/88 (81.8%)	10/110 (9.1%)	18/104 (17.3%)	11/88 (12.5%)	5/110 (4.5%)	5/104 (4.8%)	5/88 (5.7%)
Halos	100/110 (90.9%)	77/104 (74.0%)	67/88 (76.1%)	7/110 (6.4%)	20/104 (19.2%)	17/88 (19.3%)	3/110 (2.7%)	7/104 (6.7%)	4/88 (4.5%)
Blurred vision	92/110 (83.6%)	77/104 (74.0%)	69/88 (78.4%)	16/110 (14.5%)	24/104 (23.1%)	17/88 (19.3%)	2/110 (1.8%)	3/104 (2.9%)	2/88 (2.3%)
Double vision	106/110 (96.4%)	101/104 (97.1%)	87/88 (98.9%)	2/110 (1.8%)	2/104 (1.9%)	0/88 (0.0%)	2/110 (1.8%)	1/104 (1.0%)	1/88 (1.1%)
Ghost images	109/110 (99.1%)	102/104 (98.1%)	86/88 (97.7%)	1/110 (0.9%)	0/104 (0.0%)	1/88 (1.1%)	0/110 (0.0%)	2/104 (1.9%)	1/88 (1.1%)
Fluctuations of vision	100/110 (90.9%)	83/104 (79.8%)	69/88 (78.4%)	8/110 (7.3%)	18/104 (17.3%)	18/88 (20.5%)	2/110 (1.8%)	3/104 (2.9%)	1/88 (1.1%)
Variation of vision in bright light	96/110 (87.3%)	92/104 (88.5%)	78/88 (88.6%)	10/110 (9.1%)	6/104 (5.8%)	8/88 (9.1%)	4/110 (3.6%)	6/104 (5.8%)	2/88 (2.3%)
Variation of vision in normal light	109/110 (99.1%)	99/104 (95.2%)	83/88 (94.3%)	1/110 (0.9%)	5/104 (4.8%)	4/88 (4.5%)	0/110 (0.0%)	0/104 (0.0%)	1/88 (1.1%)
Variation of vision in dim light	90/110 (81.8%)	80/104 (76.9%)	65/88 (73.9%)	17/110 (15.5%)	17/104 (16.3%)	16/88 (18.2%)	3/110 (2.7%)	7/104 (6.7%)	7/88 (8.0%)
Night driving vision	78/110 (70.9%)	77/104 (74.0%)	71/88 (80.7%)	28/110 (25.5%)	19/104 (18.3%)	13/88 (14.8%)	4/110 (3.6%)	8/104 (7.7%)	4/88 (4.5%)
Discharge	109/110 (99.1%)	104/104 (100.0%)	88/88 (100.0%)	1/110 (0.9%)	0/104 (0.0%)	0/88 (0.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)
Edema, lid	109/110 (99.1%)	104/104 (100.0%)	88/88 (100.0%)	1/110 (0.9%)	0/104 (0.0%)	0/88 (0.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)
Floaters	110/110 (100.0%)	104/104 (100.0%)	88/88 (100.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)
Itching	110/110 (100.0%)	104/104 (100.0%)	88/88 (100.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)	0/110 (0.0%)	0/104 (0.0%)	0/88 (0.0%)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

At 3 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

At 6 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

Table 15: Patient Symptoms at Preop, 3 Months, & 6 Months - Eyes Treated for Astigmatic Myopia

Patient Symptoms	None n/N (%)			Mild n/N (%)			≥ Moderate n/N (%)		
	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months	Preop.	3 Months	6 Months
Light sensitivity	196/276 (71.0%)	199/266 (74.8%)	207/260 (79.6%)	49/276 (17.8%)	50/266 (18.8%)	42/260 (16.2%)	31/276 (11.2%)	17/266 (6.4%)	11/260 (4.2%)
Headaches	216/276 (78.3%)	239/266 (89.8%)	244/260 (93.8%)	28/276 (10.1%)	22/266 (8.3%)	13/260 (5.0%)	32/276 (11.6%)	5/266 (1.9%)	3/260 (1.2%)
Pain	254/276 (92.0%)	241/266 (90.6%)	250/260 (96.2%)	17/276 (6.2%)	22/266 (8.3%)	7/260 (2.7%)	5/276 (1.8%)	3/266 (1.1%)	3/260 (1.2%)
Redness	207/276 (75.0%)	223/266 (83.8%)	228/260 (87.7%)	52/276 (18.8%)	40/266 (15.0%)	24/260 (9.2%)	17/276 (6.2%)	3/266 (1.1%)	8/260 (3.1%)
Dryness	166/276 (60.1%)	163/266 (61.3%)	180/260 (69.2%)	65/276 (23.6%)	70/266 (26.3%)	66/260 (25.4%)	45/276 (16.3%)	33/266 (12.4%)	14/260 (5.4%)
Tearing	237/276 (85.9%)	249/266 (93.6%)	246/260 (94.6%)	25/276 (9.1%)	12/266 (4.5%)	11/260 (4.2%)	14/276 (5.1%)	5/266 (1.9%)	3/260 (1.2%)
Burning	233/276 (84.4%)	228/266 (85.7%)	245/260 (94.2%)	39/276 (14.1%)	35/266 (13.2%)	12/260 (4.6%)	4/276 (1.4%)	3/266 (1.1%)	3/260 (1.2%)
Gritty feeling	238/276 (86.2%)	239/266 (89.8%)	236/260 (90.8%)	32/276 (11.6%)	24/266 (9.0%)	23/260 (8.8%)	6/276 (2.2%)	3/266 (1.1%)	1/260 (0.4%)
Glare	237/276 (85.9%)	212/266 (79.7%)	225/260 (86.5%)	28/276 (10.1%)	43/266 (16.2%)	31/260 (11.9%)	11/276 (4.0%)	11/266 (4.1%)	4/260 (1.5%)
Halos	246/276 (89.1%)	180/266 (67.7%)	204/260 (78.5%)	23/276 (8.3%)	66/266 (24.8%)	48/260 (18.5%)	7/276 (2.5%)	20/266 (7.5%)	8/260 (3.1%)
Blurred vision	223/276 (80.8%)	207/266 (77.8%)	225/260 (86.5%)	36/276 (13.0%)	52/266 (19.5%)	30/260 (11.5%)	17/276 (6.2%)	7/266 (2.6%)	5/260 (1.9%)
Double vision	267/276 (96.7%)	257/266 (96.6%)	252/260 (96.9%)	9/276 (3.3%)	7/266 (2.6%)	7/260 (2.7%)	0/276 (0.0%)	2/266 (0.8%)	1/260 (0.4%)
Ghost images	269/276 (97.5%)	257/266 (96.6%)	252/260 (96.9%)	7/276 (2.5%)	7/266 (2.6%)	7/260 (2.7%)	0/276 (0.0%)	2/266 (0.8%)	1/260 (0.4%)
Fluctuations of vision	247/276 (89.5%)	213/266 (80.1%)	216/260 (83.1%)	21/276 (7.6%)	45/266 (16.9%)	37/260 (14.2%)	8/276 (2.9%)	8/266 (3.0%)	7/260 (2.7%)
Variation of vision in bright light	231/276 (83.7%)	233/266 (87.6%)	223/260 (85.8%)	37/276 (13.4%)	26/266 (9.8%)	34/260 (13.1%)	8/276 (2.9%)	7/266 (2.6%)	3/260 (1.2%)
Variation of vision in normal light	257/276 (93.1%)	230/266 (86.5%)	242/260 (93.1%)	15/276 (5.4%)	30/266 (11.3%)	12/260 (4.6%)	4/276 (1.4%)	6/266 (2.3%)	6/260 (2.3%)
Variation of vision in dim light	208/276 (75.4%)	205/266 (77.1%)	213/260 (81.9%)	55/276 (19.9%)	41/266 (15.4%)	40/260 (15.4%)	13/276 (4.7%)	20/266 (7.5%)	7/260 (2.7%)
Night driving vision	194/276 (70.3%)	214/266 (80.5%)	211/260 (81.2%)	59/276 (21.4%)	33/266 (12.4%)	38/260 (14.6%)	23/276 (8.3%)	19/266 (7.1%)	11/260 (4.2%)
Discharge	275/276 (99.6%)	266/266 (100.0%)	260/260 (100.0%)	1/276 (0.4%)	0/266 (0.0%)	0/260 (0.0%)	0/276 (0.0%)	0/266 (0.0%)	0/260 (0.0%)
Edema, lid	275/276 (99.6%)	266/266 (100.0%)	260/260 (100.0%)	1/276 (0.4%)	0/266 (0.0%)	0/260 (0.0%)	0/276 (0.0%)	0/266 (0.0%)	0/260 (0.0%)
Floaters	274/276 (99.3%)	266/266 (100.0%)	260/260 (100.0%)	2/276 (0.7%)	0/266 (0.0%)	0/260 (0.0%)	0/276 (0.0%)	0/266 (0.0%)	0/260 (0.0%)
Itching	276/276 (100.0%)	265/266 (99.6%)	260/260 (100.0%)	0/276 (0.0%)	1/266 (0.4%)	0/260 (0.0%)	0/276 (0.0%)	0/266 (0.0%)	0/260 (0.0%)

N = Number of Self-evaluation Forms received with non-missing values at each visit.

At 3 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

At 6 months, there were no symptoms graded as moderate or worse that were reported at an incidence level of more than 5% higher than the baseline incidence level.

Table 16: Summary of Key Safety and Effectiveness Variables - All Treated Eyes

Key Safety & Effectiveness Variables	3 Months		6 Months	
	n/N (%)	95%* CI	n/N (%)	95%* CI
UCVA 20/20 or better†	307/362 (84.8%)	(80.7, 88.9)	302/346 (87.3%)	(83.4, 91.2)
UCVA 20/40 or better†	360/362 (99.4%)	(98.5, 99.9)	345/346 (99.7%)	(98.7, 99.9)
MRSE‡, Attempted vs. Achieved, ± 0.50 D	309/377 (82.0%)	(77.3, 86.6)	313/361 (86.7%)	(82.8, 90.6)
MRSE‡, Attempted vs. Achieved, ± 1.00 D	367/377 (97.3%)	(95.5, 99.2)	358/361 (99.2%)	(98.1, 99.9)
MRSE‡, Attempted vs. Achieved, ± 2.00 D	377/377 (100.0%)	(99.1, 100.0)	361/361 (100.0%)	(99.1, 100.0)
MRSE‡, from Emmetropia, ± 0.50 D†	302/362 (83.4%)	(78.8, 88.1)	303/346 (87.6%)	(83.6, 91.5)
MRSE‡, from Emmetropia, ± 1.00 D†	352/362 (97.2%)	(95.4, 99.1)	344/346 (99.4%)	(98.3, 99.9)
MRSE‡, from Emmetropia, ± 2.00 D†	362/362 (100.0%)	(99.1, 100.0)	346/346 (100.0%)	(99.0, 100.0)
Loss of ≥ 2 lines BSCVA	4/376 (1.1%)	(0.1, 2.4)	3/361 (0.8%)	(0.1, 2.1)
Loss of > 2 lines BSCVA	0/376 (0.0%)	(0.0, 0.9)	0/361 (0.0%)	(0.0, 0.9)
BSCVA worse than 20/40	0/376 (0.0%)	(0.0, 0.9)	0/361 (0.0%)	(0.0, 0.9)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/362 (0.0%)	(0.0, 0.9)	0/347 (0.0%)	(0.0, 1.0)
Haze ≥ trace with loss of BSCVA > 2 lines	0/376 (0.0%)	(0.0, 0.9)	0/361 (0.0%)	(0.0, 0.9)
Increased manifest refractive astigmatism > 2.0 D¶	0/105 (0.0%)	(0.0, 3.2)	0/95 (0.0%)	(0.0, 3.5)

* Number of CRFs received with non-missing values at each visit.
† For all eyes minus those treated for monovision.
‡ MRSE = Manifest Spherical Equivalent.
¶ For eyes treated for spherical myopia only.

Table 17: Summary of Key Safety and Effectiveness Variables - Spherical Myopia Eyes

Key Safety & Effectiveness Variables	3 Months		6 Months	
	n/N (%)	95%* CI	n/N (%)	95%* CI
UCVA 20/20 or better†	88/102 (86.3%)	(79.4, 93.2)	79/92 (85.9%)	(78.4, 93.4)
UCVA 20/40 or better†	102/102 **(100.0%)**	(96.7, 100.0)	92/92 **(100.0%)**	(96.4, 100.0)
MRSE‡, Attempted vs. Achieved, ± 0.50 D	87/105 **(82.9%)**	(75.0, 90.7)	81/95 **(85.3%)**	(78.4, 92.1)
MRSE‡, Attempted vs. Achieved, ± 1.00 D	102/105 **(97.1%)**	(94.0, 99.9)	95/95 **(100.0%)**	(96.5, 100.0)
MRSE‡, Attempted vs. Achieved, ± 2.00 D	105/105 (100.0%)	(96.8, 100.0)	95/95 (100.0%)	(96.5, 100.0)
MRSE‡, from Emmetropia, ± 0.50 D†	89/102 (87.3%)	(79.9, 94.6)	82/92 (89.1%)	(82.9, 95.3)
MRSE‡, from Emmetropia, ± 1.00 D†	99/102 (97.1%)	(93.8, 99.9)	92/92 (100.0%)	(96.4, 100.0)
MRSE‡, from Emmetropia, ± 2.00 D†	102/102 (100.0%)	(96.7, 100.0)	92/92 (100.0%)	(96.4, 100.0)
Loss of ≥ 2 lines BSCVA	2/105 (1.9%)	(0.1, 6.0)	2/95 (2.1%)	(0.1, 6.6)
Loss of > 2 lines BSCVA	0/105 (0.0%)	(0.0, 3.2)	0/95 (0.0%)	(0.0, 3.5)
BSCVA worse than 20/40	0/105 (0.0%)	(0.0, 3.2)	0/95 (0.0%)	(0.0, 3.5)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/103 (0.0%)	(0.0, 3.2)	0/93 (0.0%)	(0.0, 3.6)
Haze ≥ trace with loss of BSCVA > 2 lines	0/105 (0.0%)	(0.0, 3.2)	0/95 (0.0%)	(0.0, 3.5)
Increased manifest refractive astigmatism > 2.0 D¶	0/105 (0.0%)	(0.0, 3.2)	0/95 (0.0%)	(0.0, 3.5)

* Number of CRFs received with non-missing values at each visit.
† For all eyes minus those treated for monovision.
‡ MRSE = Manifest Spherical Equivalent.
¶ For eyes treated for spherical myopia only.

Table 18: Summary of Key Safety and Effectiveness Variables - Astigmatic Myopia Eyes

Key Safety & Effectiveness Variables	3 Months		6 Months	
	n/N (%)	95%* CI	n/N (%)	95%* CI
UCVA 20/20 or better†	219/260 (84.2%)	(79.2, 89.3)	223/254 (87.8%)	(83.4, 92.2)
UCVA 20/40 or better†	258/260 **(99.2%)**	(97.9, 99.9)	253/254 **(99.6%)**	(98.3, 99.9)
MRSE‡, Attempted vs. Achieved, ± 0.50 D	222/272 **(81.6%)**	(76.1, 87.2)	232/266 **(87.2%)**	(82.7, 91.8)
MRSE‡, Attempted vs. Achieved, ± 1.00 D	265/272 **(97.4%)**	(95.2, 99.7)	263/266 **(98.9%)**	(97.4, 99.9)
MRSE‡, Attempted vs. Achieved, ± 2.00 D	272/272 (100.0%)	(98.8, 100.0)	266/266 (100.0%)	(98.7, 100.0)
MRSE‡, from Emmetropia, ± 0.50 D†	213/260 (81.9%)	(76.3, 87.6)	221/254 (87.0%)	(82.3, 91.7)
MRSE‡, from Emmetropia, ± 1.00 D†	253/260 (97.3%)	(95.1, 99.5)	252/254 (99.2%)	(97.9, 99.9)
MRSE‡, from Emmetropia, ± 2.00 D†	260/260 (100.0%)	(98.7, 100.0)	254/254 (100.0%)	(98.7, 100.0)
Loss of ≥ 2 lines BSCVA	2/271 (0.7%)	(0.1, 2.0)	1/266 (0.4%)	(0.1, 1.6)
Loss of > 2 lines BSCVA	0/271 (0.0%)	(0.0, 1.2)	0/266 (0.0%)	(0.0, 1.3)
BSCVA worse than 20/40	0/271 (0.0%)	(0.0, 1.2)	0/266 (0.0%)	(0.0, 1.3)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/259 (0.0%)	(0.0, 1.3)	0/254 (0.0%)	(0.0, 1.3)
Haze ≥ trace with loss of BSCVA > 2 lines	0/271 (0.0%)	(0.0, 1.2)	0/266 (0.0%)	(0.0, 1.3)
Increased manifest refractive astigmatism > 2.0 D¶	NA	NA	NA	NA

* Number of CRFs received with non-missing values at each visit.
† For all eyes minus those treated for monovision.
‡ MRSE = Manifest Spherical Equivalent.
¶ For eyes treated for spherical myopia only.

Table 19: Summary of Key Safety and Effectiveness Variables at 3 Months Stratified by Preoperative MRSE – All Treated Eyes

Key Safety & Effectiveness Variables	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	4.00 to 4.99 D n/N (%)	5.00 to 5.99 D n/N (%)	6.00 to 7.00 D n/N (%)	> 7.00 D n/N (%)	Total n/N (%)
Effectiveness Variables								
UCVA 20/20 or better†	18/21 (85.7%)	66/73 (90.4%)	67/80 (83.8%)	68/81 (84.0%)	48/57 (84.2%)	31/40 (77.5%)	9/10 (90.0%)	307/362 (84.8%)
UCVA 20/40 or better†	21/21 (100.0%)	73/73 (100.0%)	80/80 (100.0%)	80/81 (98.8%)	57/57 (100.0%)	39/40 (97.5%)	10/10 (100.0%)	360/362 (99.4%)
MRSE, Attempted vs. Achieved, ± 0.50 D	16/21 (76.2%)	69/77 (89.6%)	71/85 (83.5%)	73/84 (86.9%)	45/59 (76.3%)	30/41 (73.2%)	5/10 (50.0%)	309/377 (82.0%)
MRSE, Attempted vs. Achieved, ± 1.00 D	21/21 (100.0%)	76/77 (98.7%)	81/85 (95.3%)	84/84 (100.0%)	58/59 (98.3%)	39/41 (95.1%)	8/10 (80.0%)	367/377 (97.3%)
MRSE, Attempted vs. Achieved, ± 2.00 D	21/21 (100.0%)	77/77 (100.0%)	85/85 (100.0%)	84/84 (100.0%)	59/59 (100.0%)	41/41 (100.0%)	10/10 (100.0%)	377/377 (100.0%)
MRSE, from Emmetropia, ±0.50 D†	16/21 (76.2%)	65/73 (89.0%)	67/80 (83.8%)	74/81 (91.4%)	46/57 (80.7%)	29/40 (72.5%)	5/10 (50.0%)	302/362 (83.4%)
MRSE, from Emmetropia, ±1.00 D†	21/21 (100.0%)	72/73 (98.6%)	76/80 (95.0%)	81/81 (100.0%)	56/57 (98.2%)	38/40 (95.0%)	8/10 (80.0%)	352/362 (97.2%)
MRSE, from Emmetropia, ±2.00 D†	21/21 (100.0%)	73/73 (100.0%)	80/80 (100.0%)	81/81 (100.0%)	57/57 (100.0%)	40/40 (100.0%)	10/10 (100.0%)	362/362 (100.0%)
MRSPH, Attempted vs. Achieved, ± 0.50 D	15/21 (71.4%)	69/77 (89.6%)	68/85 (80.0%)	70/84 (83.3%)	49/59 (83.1%)	30/41 (73.2%)	5/10 (50.0%)	306/377 (81.2%)
MRSPH, Attempted vs. Achieved, ± 1.00 D	20/21 (95.2%)	72/77 (93.5%)	80/85 (94.1%)	84/84 (100.0%)	55/59 (93.2%)	36/41 (87.8%)	7/10 (70.0%)	354/377 (93.9%)
MRSPH, Attempted vs. Achieved, ± 2.00 D	21/21 (100.0%)	77/77 (100.0%)	85/85 (100.0%)	84/84 (100.0%)	59/59 (100.0%)	41/41 (100.0%)	10/10 (100.0%)	377/377 (100.0%)
MRSPH, from Emmetropia, ± 0.50 D†	15/21 (71.4%)	65/73 (89.0%)	64/80 (80.0%)	69/81 (85.2%)	47/57 (82.5%)	29/40 (72.5%)	5/10 (50.0%)	294/362 (81.2%)
MRSPH, from Emmetropia, ± 1.00 D†	20/21 (95.2%)	68/73 (93.2%)	75/80 (93.8%)	81/81 (100.0%)	53/57 (93.0%)	35/40 (87.5%)	7/10 (70.0%)	339/362 (93.6%)
MRSPH, from Emmetropia, ± 2.00 D†	21/21 (100.0%)	73/73 (100.0%)	80/80 (100.0%)	81/81 (100.0%)	57/57 (100.0%)	40/40 (100.0%)	10/10 (100.0%)	362/362 (100.0%)
Vector Deviation, ≤ 0.5 D‡	11/12 (91.7%)	36/51 (70.6%)	55/68 (80.9%)	54/62 (87.1%)	28/40 (70.0%)	25/30 (83.3%)	7/9 (77.8%)	216/272 (79.4%)
Vector Deviation, ≤ 1.0 D‡	11/12 (91.7%)	40/51 (78.4%)	59/68 (86.8%)	56/62 (90.3%)	32/40 (80.0%)	26/30 (86.7%)	9/9 (100.0%)	233/272 (85.7%)
Safety Variables								
Loss of ≥ 2 lines BSCVA	0/21 (0.0%)	0/76 (0.0%)	0/85 (0.0%)	2/84 (2.4%)	1/59 (1.7%)	0/41 (0.0%)	1/10 (10.0%)	4/376 (1.1%)
Loss of > 2 lines BSCVA	0/21 (0.0%)	0/76 (0.0%)	0/85 (0.0%)	0/84 (0.0%)	0/59 (0.0%)	0/41 (0.0%)	0/10 (0.0%)	0/376 (0.0%)
BSCVA worse than 20/40	0/21 (0.0%)	0/76 (0.0%)	0/85 (0.0%)	0/84 (0.0%)	0/59 (0.0%)	0/41 (0.0%)	0/10 (0.0%)	0/376 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/20 (0.0%)	0/73 (0.0%)	0/83 (0.0%)	0/82 (0.0%)	0/57 (0.0%)	0/38 (0.0%)	0/9 (0.0%)	0/362 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/21 (0.0%)	0/76 (0.0%)	0/85 (0.0%)	0/84 (0.0%)	0/59 (0.0%)	0/41 (0.0%)	0/10 (0.0%)	0/376 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/105 (0.0%)

N = Number of CRFs received with non-missing values at each visit.

* MRSPH = Manifest Sphere & MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

‡ For eyes treated for astigmatic myopia.

§ For eyes treated for spherical myopia only.

Table 20: Summary of Key Safety and Effectiveness Variables at 3 Months Stratified by Preoperative MRSE - Spherical Myopia Eyes

Key Safety & Effectiveness Variables	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	4.00 to 4.99 D n/N (%)	5.00 to 5.99 D n/N (%)	6.00 to 7.00 D n/N (%)	> 7.00 D n/N (%)	Total n/N (%)
Effectiveness Variables								
UCVA 20/20 or better†	9/9 (100.0%)	23/26 (88.5%)	11/15 (73.3%)	18/22 (81.8%)	19/19 (100.0%)	8/10 (80.0%)	0/1 (0.0%)	88/102 (86.3%)
UCVA 20/40 or better†	9/9 (100.0%)	26/26 (100.0%)	15/15 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	10/10 (100.0%)	1/1 (100.0%)	102/102 (100.0%)
MRSE, Attempted vs. Achieved, ± 0.50 D	7/9 (77.8%)	25/26 (96.2%)	12/17 (70.6%)	18/22 (81.8%)	15/19 (78.9%)	9/11 (81.8%)	1/1 (100.0%)	87/105 (82.9%)
MRSE, Attempted vs. Achieved, ± 1.00 D	9/9 (100.0%)	26/26 (100.0%)	15/17 (88.2%)	22/22 (100.0%)	19/19 (100.0%)	10/11 (90.9%)	1/1 (100.0%)	102/105 (97.1%)
MRSE, Attempted vs. Achieved, ± 2.00 D	9/9 (100.0%)	26/26 (100.0%)	17/17 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	11/11 (100.0%)	1/1 (100.0%)	105/105 (100.0%)
MRSE, from Emmetropia, ±0.50 D†	7/9 (77.8%)	25/26 (96.2%)	11/15 (73.3%)	20/22 (90.9%)	17/19 (89.5%)	8/10 (80.0%)	1/1 (100.0%)	89/102 (87.3%)
MRSE, from Emmetropia, ±1.00 D†	9/9 (100.0%)	26/26 (100.0%)	13/15 (86.7%)	22/22 (100.0%)	19/19 (100.0%)	9/10 (90.0%)	1/1 (100.0%)	99/102 (97.1%)
MRSE, from Emmetropia, ±2.00 D†	9/9 (100.0%)	26/26 (100.0%)	15/15 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	10/10 (100.0%)	1/1 (100.0%)	102/102 (100.0%)
MRSPH, Attempted vs. Achieved, ± 0.50 D	6/9 (66.7%)	26/26 (100.0%)	11/17 (64.7%)	19/22 (86.4%)	17/19 (89.5%)	9/11 (81.8%)	1/1 (100.0%)	89/105 (84.8%)
MRSPH, Attempted vs. Achieved, ± 1.00 D	9/9 (100.0%)	26/26 (100.0%)	15/17 (88.2%)	22/22 (100.0%)	18/19 (94.7%)	9/11 (81.8%)	1/1 (100.0%)	100/105 (95.2%)
MRSPH, Attempted vs. Achieved, ± 2.00 D	9/9 (100.0%)	26/26 (100.0%)	17/17 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	11/11 (100.0%)	1/1 (100.0%)	105/105 (100.0%)
MRSPH, from Emmetropia, ± 0.50 D†	6/9 (66.7%)	26/26 (100.0%)	10/15 (66.7%)	19/22 (86.4%)	17/19 (89.5%)	8/10 (80.0%)	1/1 (100.0%)	87/102 (85.3%)
MRSPH, from Emmetropia, ± 1.00 D†	9/9 (100.0%)	26/26 (100.0%)	13/15 (86.7%)	22/22 (100.0%)	18/19 (94.7%)	8/10 (80.0%)	1/1 (100.0%)	97/102 (95.1%)
MRSPH, from Emmetropia, ± 2.00 D†	9/9 (100.0%)	26/26 (100.0%)	15/15 (100.0%)	22/22 (100.0%)	19/19 (100.0%)	10/10 (100.0%)	1/1 (100.0%)	102/102 (100.0%)
Vector Deviation, ≤ 0.5 D‡	NA	NA	NA	NA	NA	NA	NA	NA
Vector Deviation, ≤ 1.0 D‡	NA	NA	NA	NA	NA	NA	NA	NA
Safety Variables								
Loss of ≥ 2 lines BSCVA	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	1/22 (4.5%)	1/19 (5.3%)	0/11 (0.0%)	0/1 (0.0%)	2/105 (1.9%)
Loss of > 2 lines BSCVA	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/105 (0.0%)
BSCVA worse than 20/40	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/105 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/8 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/21 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/103 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/105 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	0/9 (0.0%)	0/26 (0.0%)	0/17 (0.0%)	0/22 (0.0%)	0/19 (0.0%)	0/11 (0.0%)	0/1 (0.0%)	0/105 (0.0%)

N = Number of CRFs received with non-missing values at each visit.

* MRSPH = Manifest Sphere & MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

‡ For eyes treated for astigmatic myopia.

§ For eyes treated for spherical myopia only.

Table 21: Summary of Key Safety and Effectiveness Variables at 3 Months Stratified By Preoperative MRSE - Astigmatic Myopia Eyes

Key Safety & Effectiveness Variables	1.00 to 1.99 D n/N (%)	2.00 to 2.99 D n/N (%)	3.00 to 3.99 D n/N (%)	4.00 to 4.99 D n/N (%)	5.00 to 5.99 D n/N (%)	6.00 to 7.00 D n/N (%)	> 7.00 D n/N (%)	Total n/N (%)
Effectiveness Variables								
UCVA 20/20 or better†	9/12 (75.0%)	43/47 (91.5%)	56/65 (86.2%)	50/59 (84.7%)	29/38 (76.3%)	23/30 (76.7%)	9/9 (100.0%)	219/260 (84.2%)
UCVA 20/40 or better†	12/12 (100.0%)	47/47 (100.0%)	65/65 (100.0%)	58/59 (98.3%)	38/38 (100.0%)	29/30 (96.7%)	9/9 (100.0%)	258/260 (99.2%)
MRSE, Attempted vs. Achieved, ± 0.50 D	9/12 (75.0%)	44/51 (86.3%)	59/68 (86.8%)	55/62 (88.7%)	30/40 (75.0%)	21/30 (70.0%)	4/9 (44.4%)	222/272 (81.6%)
MRSE, Attempted vs. Achieved, ± 1.00 D	12/12 (100.0%)	50/51 (98.0%)	66/68 (97.1%)	62/62 (100.0%)	39/40 (97.5%)	29/30 (96.7%)	7/9 (77.8%)	265/272 (97.4%)
MRSE, Attempted vs. Achieved, ± 2.00 D	12/12 (100.0%)	51/51 (100.0%)	68/68 (100.0%)	62/62 (100.0%)	40/40 (100.0%)	30/30 (100.0%)	9/9 (100.0%)	272/272 (100.0%)
MRSE, from Emmetropia, ±0.50 D†	9/12 (75.0%)	40/47 (85.1%)	56/65 (86.2%)	54/59 (91.5%)	29/38 (76.3%)	21/30 (70.0%)	4/9 (44.4%)	213/260 (81.9%)
MRSE, from Emmetropia, ± 1.00 D†	12/12 (100.0%)	46/47 (97.9%)	63/65 (96.9%)	59/59 (100.0%)	37/38 (97.4%)	29/30 (96.7%)	7/9 (77.8%)	253/260 (97.3%)
MRSE, from Emmetropia, ±2.00 D†	12/12 (100.0%)	47/47 (100.0%)	65/65 (100.0%)	59/59 (100.0%)	38/38 (100.0%)	30/30 (100.0%)	9/9 (100.0%)	260/260 (100.0%)
MRSPH, Attempted vs. Achieved, ± 0.50 D	9/12 (75.0%)	43/51 (84.3%)	57/68 (83.8%)	51/62 (82.3%)	32/40 (80.0%)	21/30 (70.0%)	4/9 (44.4%)	217/272 (79.8%)
MRSPH, Attempted vs. Achieved, ± 1.00 D	11/12 (91.7%)	46/51 (90.2%)	65/68 (95.6%)	62/62 (100.0%)	37/40 (92.5%)	27/30 (90.0%)	6/9 (66.7%)	254/272 (93.4%)
MRSPH, Attempted vs. Achieved, ± 2.00 D	12/12 (100.0%)	51/51 (100.0%)	68/68 (100.0%)	62/62 (100.0%)	40/40 (100.0%)	30/30 (100.0%)	9/9 (100.0%)	272/272 (100.0%)
MRSPH, from Emmetropia, ± 0.50 D†	9/12 (75.0%)	39/47 (83.0%)	54/65 (83.1%)	50/59 (84.7%)	30/38 (78.9%)	21/30 (70.0%)	4/9 (44.4%)	207/260 (79.6%)
MRSPH, from Emmetropia, ± 1.00 D†	11/12 (91.7%)	42/47 (89.4%)	62/65 (95.4%)	59/59 (100.0%)	35/38 (92.1%)	27/30 (90.0%)	6/9 (66.7%)	242/260 (93.1%)
MRSPH, from Emmetropia, ± 2.00 D†	12/12 (100.0%)	47/47 (100.0%)	65/65 (100.0%)	59/59 (100.0%)	38/38 (100.0%)	30/30 (100.0%)	9/9 (100.0%)	260/260 (100.0%)
Vector Deviation, ≤ 0.5 D‡	11/12 (91.7%)	36/51 (70.6%)	55/68 (80.9%)	54/62 (87.1%)	28/40 (70.0%)	25/30 (83.3%)	7/9 (77.8%)	216/272 (79.4%)
Vector Deviation, ≤ 1.0 D‡	11/12 (91.7%)	40/51 (78.4%)	59/68 (86.8%)	56/62 (90.3%)	32/40 (80.0%)	26/30 (86.7%)	9/9 (100.0%)	233/272 (85.7%)
Safety Variables								
Loss of ≥ 2 lines BSCVA	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	1/62 (1.6%)	0/40 (0.0%)	0/30 (0.0%)	1/9 (11.1%)	2/271 (0.7%)
Loss of > 2 lines BSCVA	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)	0/271 (0.0%)
BSCVA worse than 20/40	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)	0/271 (0.0%)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/12 (0.0%)	0/47 (0.0%)	0/66 (0.0%)	0/61 (0.0%)	0/38 (0.0%)	0/27 (0.0%)	0/8 (0.0%)	0/259 (0.0%)
Haze ≥ trace with loss of BSCVA > 2 lines	0/12 (0.0%)	0/50 (0.0%)	0/68 (0.0%)	0/62 (0.0%)	0/40 (0.0%)	0/30 (0.0%)	0/9 (0.0%)	0/271 (0.0%)
Increased manifest refractive astigmatism > 2.0 D§	NA	NA	NA	NA	NA	NA	NA	NA

N = Number of CRFs received with non-missing values at each visit.

* MRSPH = Manifest Sphere & MRSE = Manifest Spherical Equivalent.

† For all eyes minus those treated for monovision

‡ For eyes treated for astigmatic myopia.

§ For eyes treated for spherical myopia only.

Table 22: Report of the Residual Astigmatic Error at 3 And 6 Months - Eyes Treated for Astigmatic Myopia

Residual Manifest Cylinder Magnitude	Absolute Shift in Manifest Axis ≤ 5° n/N (%)	> 5° to ≤ 10° n/N (%)	> 10° to ≤ 15° N/N (%)	> 15° to ≤ 30° n/N (%)	> 30° n/N (%)	Total n/N (%)
3 Months, Mean (SD) of Cylinder = -0.28 (0.33)						
0 to < 0.5 D	39/272 (14.3%)	23/272 (8.5%)	20/272 (7.4%)	20/272 (7.4%)	66/272 (24.3%)	168/272 (61.8%)
≥ 0.5 to < 1.0 D	17/272 (6.3%)	9/272 (3.3%)	13/272 (4.8%)	15/272 (5.5%)	39/272 (14.3%)	93/272 (34.2%)
≥ 1.0 to < 2.0 D	3/272 (1.1%)	2/272 (0.7%)	2/272 (0.7%)	0/272 (0.0%)	3/272 (1.1%)	10/272 (3.7%)
≥ 2.0 to < 3.0 D	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)	1/272 (0.4%)	1/272 (0.4%)
≥ 3.0 D	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)	0/272 (0.0%)
Total	59/272 (21.7%)	34/272 (12.5%)	35/272 (12.9%)	35/272 (12.9%)	109/272 (40.1%)	272/272 (100.0%)
6 Months, Mean (SD) of Cylinder = -0.26 (0.31)						
0 to < 0.5 D	38/266 (14.3%)	24/266 (9.0%)	22/266 (8.3%)	20/266 (7.5%)	65/266 (24.4%)	169/266 (63.5%)
≥ 0.5 to < 1.0 D	15/266 (5.6%)	9/266 (3.4%)	11/266 (4.1%)	16/266 (6.0%)	32/266 (12.0%)	83/266 (31.2%)
≥ 1.0 to < 2.0 D	4/266 (1.5%)	0/266 (0.0%)	1/266 (0.4%)	3/266 (1.1%)	6/266 (2.3%)	14/266 (5.3%)
≥ 2.0 to < 3.0 D	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)
≥ 3.0 D	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)	0/266 (0.0%)
Total	57/266 (21.4%)	33/266 (12.4%)	34/266 (12.8%)	39/266 (14.7%)	103/266 (38.7%)	266/266 (100.0%)

N = # of CRFs with non-missing value.

96.0% and 94.7% of eyes had a residual cylinder of less than 1.0 D at 3 and 6 months, respectively.

Table 23: Report of Residual Astigmatic Error at 3 Months Stratified by Preoperative Diopter of Absolute Cylinder- Astigmatic Myopia Eyes

Preoperative Diopter of Absolute Cylinder	Residual Manifest Cylinder Magnitude	Absolute Shift in Manifest Axis ≤ 5° n/N (%)	> 5° to ≤ 10° n/N (%)	> 10° to ≤ 15° n/N (%)	> 15° to ≤ 30° n/N (%)	> 30° n/N (%)	Total n/N (%)
Preoperative Manifest Cylinder < 1.00 D	0 to < 0.5 D	21/144 (14.6%)	15/144 (10.4%)	10/144 (6.9%)	13/144 (9.0%)	42/144 (29.2%)	101/144 (70.1%)
Not reported = 0	≥ 0.5 to < 1.0 D	6/144 (4.2%)	7/144 (4.9%)	5/144 (3.5%)	5/144 (3.5%)	20/144 (13.9%)	43/144 (29.9%)
# of CRFs with non-missing value = 144	≥ 1.0 to < 2.0 D	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)
Total # of CRFs received = 144	≥ 2.0 to < 3.0 D	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)
	≥ 3.0 D	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)	0/144 (0.0%)
	Total	27/144 (18.8%)	22/144 (15.3%)	15/144 (10.4%)	18/144 (12.5%)	62/144 (43.1%)	144/144 (100.0%)
Preoperative Manifest Cylinder 1.00 to 1.99 D	0 to < 0.5 D	12/89 (13.5%)	7/89 (7.9%)	6/89 (6.7%)	5/89 (5.6%)	16/89 (18.0%)	46/89 (51.7%)
Not reported = 0	≥ 0.5 to < 1.0 D	6/89 (6.7%)	1/89 (1.1%)	6/89 (6.7%)	7/89 (7.9%)	14/89 (15.7%)	34/89 (38.2%)
# of CRFs with non-missing value = 89	≥ 1.0 to < 2.0 D	3/89 (3.4%)	2/89 (2.2%)	1/89 (1.1%)	0/89 (0.0%)	2/89 (2.2%)	8/89 (9.0%)
Total # of CRFs received = 89	≥ 2.0 to < 3.0 D	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)	1/89 (1.1%)	1/89 (1.1%)
	≥ 3.0 D	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)	0/89 (0.0%)
	Total	21/89 (23.6%)	10/89 (11.2%)	13/89 (14.6%)	12/89 (13.5%)	33/89 (37.1%)	89/89 (100.0%)
Preoperative Manifest Cylinder 2.00 to 2.99 D	0 to < 0.5 D	6/34 (17.6%)	1/34 (2.9%)	4/34 (11.8%)	2/34 (5.9%)	7/34 (20.6%)	20/34 (58.8%)
Not reported = 0	≥ 0.5 to < 1.0 D	5/34 (14.7%)	0/34 (0.0%)	1/34 (2.9%)	2/34 (5.9%)	5/34 (14.7%)	13/34 (38.2%)
# of CRFs with non-missing value = 34	≥ 1.0 to < 2.0 D	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	1/34 (2.9%)	1/34 (2.9%)
Total # of CRFs received = 34	≥ 2.0 to < 3.0 D	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)
	≥ 3.0 D	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)	0/34 (0.0%)
	Total	11/34 (32.4%)	1/34 (2.9%)	5/34 (14.7%)	4/34 (11.8%)	13/34 (38.2%)	34/34 (100.0%)
Preoperative Manifest Cylinder 3.00 to 3.99 D	0 to < 0.5 D	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	1/5 (20.0%)	1/5 (20.0%)
Not reported = 0	≥ 0.5 to < 1.0 D	0/5 (0.0%)	1/5 (20.0%)	1/5 (20.0%)	1/5 (20.0%)	0/5 (0.0%)	3/5 (60.0%)
# of CRFs with non-missing value = 5	≥ 1.0 to < 2.0 D	0/5 (0.0%)	0/5 (0.0%)	1/5 (20.0%)	0/5 (0.0%)	0/5 (0.0%)	1/5 (20.0%)
Total # of CRFs received = 5	≥ 2.0 to < 3.0 D	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)
	≥ 3.0 D	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)	0/5 (0.0%)
	Total	0/5 (0.0%)	1/5 (20.0%)	2/5 (40.0%)	1/5 (20.0%)	1/5 (20.0%)	5/5 (100.0%)

Table 24: Vector Magnitude Analysis Summary at 3 And 6 Months - Eyes Treated for Astigmatic Myopia

With Complete Preoperative and Postoperative Refraction

Statistics	Preoperative	Postoperative	IRC	SIRC	SIRC/IRC*
3 Months (No eyes were reported with an IRC = 0.)					
N	272	272	272	272	272
Mean	-1.07	-0.28	1.07	1.03	0.99
Median	-0.75	-0.25	0.75	0.75	1.00
Standard Deviation	0.67	0.33	0.67	0.68	0.35
Minimum	-3.50	-2.00	0.25	0.02	0.03
Maximum	-0.25	0.00	3.50	3.50	3.00
6 Months (No eyes were reported with an IRC = 0.)					
N	266	266	266	266	266
Mean	-1.07	-0.26	1.07	1.03	0.99
Median	-0.75	0.00	0.75	0.75	1.00
Standard Deviation	0.67	0.31	0.67	0.69	0.35
Minimum	-3.50	-1.25	0.25	0.00	0.00
Maximum	-0.25	0.00	3.50	4.00	2.96

* Data with an IRC = 0 were excluded from the 'SIRC/IRC' column.

IRC = square root of (preop ×preop + itt ×itt - 2 ×preop ×itt ×cos).

SIRC = square root of (preop ×preop + postop ×postop - 2 ×preop ×postop ×cos.)

Where preop = preop cylinder, postop = postop cylinder, itt = intended postop cylinder, & cos = cosine of the axis difference between preop & itt or preop & postop.

Table 25: Cylinder Correction Effectiveness Stratified by Preoperative Cylinder - Astigmatic Myopia

With Complete Preoperative and Postoperative Refraction

Preoperative Cylinder	Percent Reduction of Absolute Cylinder (Not Vector)			Achieved vs Intended Vector Magnitude Ratio (SIRC/IRC*)		
	N	Mean (SD)	Median (Range)	N	Mean (SD)	Median (Range)
1 Month (0 eye was reported with an IRC = 0.)						
< 1.00 D	140	61.43 (55.84)	100.00 (-200.0 to 100.00)	140	1.06 (0.42)	1.00 (0.00 to 2.44)
1.00 to 1.99 D	86	76.78 (28.40)	85.71 (-20.00 to 100.00)	86	0.97 (0.27)	1.00 (0.00 to 1.74)
2.00 to 2.99 D	33	91.69 (14.97)	100.00 (54.55 to 100.00)	33	0.97 (0.13)	1.00 (0.67 to 1.29)
3.00 to 3.99 D	5	75.48 (13.14)	83.33 (58.33 to 85.71)	5	0.82 (0.13)	0.86 (0.67 to 0.96)
Total	264	70.48 (45.30)	100.00 (-200.0 to 100.00)	264	1.02 (0.35)	1.00 (0.00 to 2.44)
3 Months (0 eye was reported with an IRC = 0.)						
< 1.00 D	144	62.50 (51.27)	100.00 (-200.0 to 100.00)	144	1.03 (0.41)	1.00 (0.03 to 3.00)
1.00 to 1.99 D	89	69.27 (32.50)	75.00 (-33.33 to 100.00)	89	0.94 (0.31)	1.00 (0.17 to 1.75)
2.00 to 2.99 D	34	87.70 (13.86)	94.44 (60.00 to 100.00)	34	0.97 (0.16)	1.00 (0.63 to 1.38)
3.00 to 3.99 D	5	82.62 (15.10)	85.71 (58.33 to 100.00)	5	0.86 (0.12)	0.87 (0.67 to 1.00)
Total	272	68.23 (42.73)	85.71 (-200.0 to 100.00)	272	0.99 (0.35)	1.00 (0.03 to 3.00)
6 Months (0 eye was reported with an IRC = 0.)						
< 1.00 D	140	65.36 (50.02)	100.00 (-100.0 to 100.00)	140	1.04 (0.40)	1.00 (0.00 to 2.96)
1.00 to 1.99 D	88	70.98 (32.61)	77.50 (-25.00 to 100.00)	88	0.92 (0.33)	1.00 (0.00 to 2.18)
2.00 to 2.99 D	33	87.56 (13.84)	88.89 (60.00 to 100.00)	33	0.98 (0.15)	1.00 (0.66 to 1.38)
3.00 to 3.99 D	5	83.33 (12.14)	85.71 (66.67 to 100.00)	5	0.95 (0.15)	0.99 (0.73 to 1.14)
Total	266	70.31 (41.72)	100.00 (-100.0 to 100.00)	266	0.99 (0.35)	1.00 (0.00 to 2.96)

* Data with an IRC = 0 were excluded from the 'SIRC/IRC' calculation.

Percent Reduction of Absolute Cylinder = Reduction of Absolute Cylinder ÷ Preop. Cylinder × 100. A negative value means an increase in astigmatism.

IRC = square root of (preop ×preop + itt ×itt - 2 ×preop ×itt ×cos).

SIRC = square root of (preop ×preop + postop ×postop - 2 ×preop ×postop ×cos.)

Where preop = preop cylinder, postop = postop cylinder, itt = intended postop cylinder, & cos = cosine of the axis difference between preop & itt opreop & postop.

Table 26 : Generalized Estimating Equation Outcomes Summary

Effectiveness Variables	Statistically Significant Predictors	Statistical Conclusion
UCVA 20/40 or Better at 3 and 6 Months	***age***	An older subject is associated with a lower success rate.
MRSPH Deviation from Attempted Correction within ± 1.00 D at 3 and 6 Months	***postoperative visit***	6-Month is associated with a higher success rate.
MRSPH Deviation from Attempted Correction within ± 0.50 D at 3 and 6 Months	***age***	An older subject is associated with a lower success rate.
	study site	Site "TORONTO" is associated with a relatively higher success rate.
	postoperative visit	6-Month is associated with a higher success rate.
Manifest Vector Deviation ≤ 1.00 D at 3 and 6 Months	***preoperative cylinder***	A higher preoperative cylinder is associated with a higher success rate.
Manifest Vector Deviation ≤ 0.50 D at 3 and 6 Months	***gender***	Male is associated with a higher success rate.

MRSPH = Manifest Refractive Sphere

Table 27: Self-Evaluation at 3 Months

Overall Quality of Vision, Choose Again, & Satisfaction - All Treated Eyes

Self-Evaluation Questions	Response	Overall n/N (%)	Spherical Myopia n/N (%)	Astigmatic Myopia n/N (%)
Overall Quality of Vision after Excimer Laser	No Improvement	0/362 (0.0%)	0/100 (0.0%)	0/262 (0.0%)
	Slight Improvement	1/362 (0.3%)	1/100 (1.0%)	0/262 (0.0%)
	Moderate Improvement	13/362 (3.6%)	4/100 (4.0%)	9/262 (3.4%)
	Marked Improvement	106/362 (29.3%)	29/100 (29.0%)	77/262 (29.4%)
	Extreme Improvement	242/362 (66.9%)	66/100 (66.0%)	176/262 (67.2%)
	Not reported*	8	4	4
	Total†	370	104	266
Choose Excimer Again?	No	0/365 (0.0%)	0/100 (0.0%)	0/265 (0.0%)
	Unsure	6/365 (1.6%)	2/100 (2.0%)	4/265 (1.5%)
	Yes	359/365 (98.4%)	98/100 (98.0%)	261/265 (98.5%)
	Not reported*	5	4	1
	Total†	370	104	266
How Satisfied with the Excimer Laser Results?	Very Satisfied	334/367 (91.0%)	88/102 (86.3%)	246/265 (92.8%)
	Moderately Satisfied	28/367 (7.6%)	12/102 (11.8%)	16/265 (6.0%)
	Neutral	4/367 (1.1%)	2/102 (2.0%)	2/265 (0.8%)
	Dissatisfied	1/367 (0.3%)	0/102 (0.0%)	1/265 (0.4%)
	Very Dissatisfied	0/367 (0.0%)	0/102 (0.0%)	0/265 (0.0%)
	Not reported*	3	2	1
	Total†	370	104	266

N = Number of CRFs received with non-missing values at each visit.

* Number of CRFs received with missing values at each visit.

† Number of CRFs received at each visit.